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#### **PURPOSE**

HIV can be passed from an HIV-positive mother to her baby through breast milk. The risk is lower when the mother's viral load is undetectable, but there is still a potential risk. To enable women who are living with HIV in Saskatchewan to provide safe and appropriate nutrition to their newborns, free formula is available through the Saskatchewan Infant Formula Program.

#### **BACKGROUND AND ETHICAL CONSIDERATIONS**

On average, approximately 40 women living with HIV deliver babies in Saskatchewan annually. For updated statistics, go to www.saskatchewan.ca/hiv to review the annual HIV Prevention and Control Report.

Breastfeeding presents an ongoing risk of HIV exposure after birth; therefore, the safest way to feed infants born to women living with HIV is with formula. Suppressive maternal antiretroviral therapy significantly reduces, but does not eliminate, the risk of transmitting HIV through breastfeeding. Therefore, breastfeeding is not recommended for women living with HIV. Women who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counselling on infant feeding options.

#### **PROCEDURES**

#### 1. Referral:

Each woman should be referred to the SK Infant Formula Program during pregnancy to begin the enrollment and education process. Referrals can be made by healthcare professionals, nurses, physicians, or by the individual as a self-referral. Each person eligible for enrollment in the program will be referred to one of three Infant Formula Program Coordinators. The location chosen should be the one that best suits the home location of the mother/caregiver:

 Prince Albert
 Phone: 306-765-6535

 Regina
 Phone: 306-766-3915

 Saskatoon
 Phone: 306-655-1783

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#### 2. Eligibility:

Infant Formula Program Coordinators will determine the eligibility of mothers/caregivers under the following federal or provincial programs:

#### Non-Insured Health Benefits (NIHB) – Infant Formula

Non-Insured Health Benefits (NIHB) is a limited use benefit in which prior approval is required. The NIHB Infant Formula Program is for women with Treaty status and covers the cost of infant formula for babies less than 1 year of age (corrected gestational age for prematurity), if medically necessary. \*Examples of medically necessary conditions include contraindications for breastfeeding (i.e., mothers living with HIV, hepatitis C, active tuberculosis, and herpetic breast lesions), cow's milk protein allergy, failure to thrive, prematurity, or low birth weight. On an exception basis, other conditions may be considered with the appropriate rationale for medically necessary. For all cases, a prescription must be sent by a physician.

Further information on types of formula covered can be found at: <a href="https://www.sac-isc.gc.ca/eng/1574358650814/1574358746154">https://www.sac-isc.gc.ca/eng/1574358650814/1574358746154</a>

For mothers living with HIV awaiting the approval of the limited use benefit, the Saskatchewan Infant Formula Program may be accessed on a short-term basis.

\* The Saskatchewan Infant Formula Policy and Procedures only pertains to mothers living with HIV; for all other medically necessary conditions as outlined above, refer to: <a href="https://www.sac-isc.gc.ca/eng/1576790320164/1576790364553">https://www.sac-isc.gc.ca/eng/1576790320164/1576790364553</a>.

#### **Community-Based Organizations**

Some community-based organizations in Saskatoon and Regina provide free formula; however, there are some limitations, including:

- Availability is determined by each organization and they may limit access to clients already on social assistance and/or limit the amount of formula received over a defined period.
- Brand and type of formula may vary based on donations.
- Some organizations may require HIV disclosure. If clients are required to disclose their HIV status, this
  could limit access due to stigma and/or fear of privacy not being met. If they do not disclose their HIV
  status, they may not be deemed eligible.

#### Social Assistance and Saskatchewan Income Support Programs

For individuals on Social Assistance Programs (SAP), the client must pay the initial \$70 per month and SAP will reimburse the individual for any formula expenses above \$70 with the appropriate receipts.

Clients on Saskatchewan Income Support (SIS) programs are provided with a monthly allowance of \$50 for formula costs.

Any costs may be a barrier to accessing formula for infants; therefore, clients on SAP and SIS are eligible to receive free formula through the Saskatchewan Infant Formula Program.

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#### Saskatchewan Infant Formula Program

Infants born to women who are HIV-positive are eligible for the Saskatchewan Infant Formula Program from birth to 1 year of age (corrected gestational age for prematurity). This program is inclusive of all infants, regardless of provincial or federal benefits status. Through the Saskatchewan Infant Formula Program, each infant is eligible to receive up to 4 cases of formula per month until the infant reaches 1 year of age. Note: this is equivalent to a maximum of 48 cases of formula over the 12-month period.

The only exemption from the program is a child in the care of Child and Family Services that is eligible to access funding for formula through the Ministry of Social Services. If an infant transitions from Child and Family Services back to their mother/caregiver prior to 1 year of age, the infant will be eligible for the Saskatchewan Infant Formula Program. For more information on Child and Family Services formula funding, refer to: <a href="https://www.saskatchewan.ca/government/government-structure/ministries/social-services">https://www.saskatchewan.ca/government/government-structure/ministries/social-services</a>.

The Infant Formula Program Coordinator would complete the following steps to facilitate enrollment in the program and access to formula:

- i. Fill out the "Participant Intake Form" (Appendix A) and help find a convenient pharmacy or venue for the mother/caregiver to pick up the formula on a regular basis. Provide the client with the "Participant Information Sheet" (Appendix E).
  - a) If there are no existing pharmacies/venues that are a suitable location for the mother/caregiver to pick up the formula, the Infant Formula Program Coordinator must initially approach the pharmacy manager of the prospective community partner by phone and provide the "Letter to Prospective Pharmacy" (Appendix B), "Program Information for Pharmacist" (Appendix C), and a blank "Infant Formula Requisition Form (Appendix D).
- ii. Once a suitable pharmacy/venue has been established, fill out the "Program Information for Pharmacist" (Appendix C) and "Infant Formula Requisition Form" (Appendix D) and forward these to the pharmacy. A 4-week supply will be ordered at one time, unless other intervals have been arranged.
- iii. Instruct the mother/caregiver to contact the Infant Formula Program Coordinator when there is only 1 case left of formula (or 1 week's supply). This will allow adequate time for the coordinator to contact the pharmacy with the "Infant Formula Requisition Form" (Appendix D) as well as for the pharmacy to order and receive the formula. This process maintains engagement of the client and limits wastage if the infant is intolerant of the formula or the family moves.

To explore formula options, while the infant is enrolled in the program, the mother/caregiver may be given the opportunity to connect with a dietician and healthcare team. Changes of formula type are permitted for intolerance, but lactose-free or special needs formula must be requested by a dietician or specialist. The requests must be sent to the Infant Formula Program Coordinator. Additional requests outside of the products provided under the program will be reviewed on an as-needed basis.

Products offered under the Saskatchewan Infant Formula Program include:

- Similac Advance
- Nestle Good Start with Omega 3 & 6
- Enfamil A+

Confidentiality of the individuals enrolled in the program will always be maintained. Each location may operate differently to best meet the needs of their community.

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#### 3. Client Support:

The Infant Formula Program Coordinator will arrange for education on the product. Education may be provided by appropriate nursing staff or dietician. The educator will ensure the mother/caregiver understands how to prepare and administer the formula safely and appropriately. It is also important for the Infant Formula Program Coordinator to prepare the mother/caregiver for the transition off the SK Infant Formula Program prior to the infant's one-year birthday. This may require referrals to other agencies.

#### 4. Billing:

There will be no costs incurred by the mother/caregiver.

The pharmacy will bill the costs directly to the Infant Formula Program Coordinator, c/o Saskatchewan Prevention Institute. The Saskatchewan Prevention Institute credit card information should be included on the requisition forms for the pharmacy (Appendix D).

#### 5. Accountability:

In order to monitor and evaluate the program, the Infant Formula Program Coordinators are to keep annual statistics using the template outlined in Appendix F. De-identified statistics are to be submitted annually to the Saskatchewan Prevention Institute by faxing the form to 306-651-4301 or by email to <a href="mailto:contact@skhiv.ca">contact@skhiv.ca</a>.

Infant Formula Program Coordinators are to obtain receipts from dispensing pharmacy for each amount of formula provided. De-identified receipts are to be sent to Saskatchewan Prevention Institute for account reconciliation monthly through fax at 306-651-4301. Original receipts and annual statistics are to be kept on file by Infant Formula Program Coordinators.

Infant Formula Program Coordinators are to contact the pharmacy and the Saskatchewan Prevention Institute one month before the infant turns one year of age to advise the date the infant will no longer be eligible for the program.

Questions regarding the formula program can be directed to contact@skhiv.ca or by calling 306-651-4311.

Regular teleconferences will occur with the Infant Formula Program Coordinators, Saskatchewan Prevention Institute, and SHA provincial HIV Nurse Consultant to discuss operational issues and continue monitoring the program.

#### **APPENDICES**

- Appendix A: Participant Intake Form Template
- Appendix B: Letter to Prospective Pharmacy
- Appendix C: Program Information for Pharmacist
- Appendix D: Infant Formula Requisition Form
- Appendix E: Participant Information Sheet
- Appendix F: Example of Tracking Form
- Appendix G: Example of Roll-up of Provincial Statistics

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# Appendix A Participant Intake Form - Template

Date:	
Referred by:	Saskatchewan Prevention Institute  1319 Colony Street  Saskatoon, SK S7N 2Z1
Phone:	Fax:
PARTICIPANT DEMOGRAPHICS	
Last Name:	Phone:
First Name:	Alternate Phone:
PHN:	Text: ☐ Yes ☐ No
DOB:	Case Manager/Support Person:
Treaty: 🗆 Yes 🗆 No	
Reserve: ☐ On ☐ Off ☐ N/A	
Interpretation Needed:	
If Yes, Language:	Mother prescribed methadone: ☐ Yes ☐ No
BABY INFORMATION	
Name:	HSN:
Baby DOB:	Formula Program End Date:
Dietitian notified of birth: ☐ No ☐ Yes If Yes,	Date:
FORMULA ORDERING INFORMATION	
Pharmacy:	Store Number:
Address:	Phone:
	Fax:
Formula Choice:	
Other Information:	
Dietitian notified of intake: ☐ No ☐ Yes If Yes	s, Date:

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### Appendix B Letter to Prospective Pharmacy

Attention: Community Pharmacy Manager

Thank you for being willing to learn more about and possibly become a community partner with the Saskatchewan Infant Formula Program. This program is funded by the Ministry of Health and is administered by the Saskatchewan Prevention Institute.

Some key points about the program which may be useful to you:

- It is a special program for families in need of formula for the first year of their baby's life.
- The volume of participants is quite low; therefore, it should not add too much workload to your business.
- Formula is ordered as needed so there will be no need to carry a stock supply.
- Formula is typically ordered in intervals of once per month, averaging 4 cases per order, and is ordered by the Infant Formula Program Coordinator via a requisition.
- There should be no cost to you. Upon placing the order, you can immediately charge a corporate credit card so you do not need to wait for reimbursement.
- The Ministry of Health has allowed a 5% mark-up above the acquisition cost to assist in processing fees.

Additionally, I have attached two documents that provide details about the role of a pharmacy acting as a community partner for the Saskatchewan Infant Formula Program.

- 1. **Program Information for Pharmacist** this document explains the step-by-step process of the Saskatchewan Infant Formula Program from a pharmacy perspective.
- 2. *Infant Formula Requisition Form* this is a sample form to show you the appearance of the formula requisition.

Please do not hesitate to contact me if you have any questions, comments, or concerns as well as if you would like to become a community partner in this important program.

Sincerely,

Infant Formula Program Coordinator

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### Appendix C Program Information for Pharmacist

Thank you for agreeing to participate in this Ministry of Health funded program to provide infant formula to infants supported by this initiative. Formula needs are supported for the first year of the infant's life.

Please refer to the following step-by-step instructions for the program:

- 1. Infant formula is ordered only by a requisition. Unless other arrangements have been made, orders are sent typically once per month and will be 4 cases of concentrated liquid. Only certain formula brands are approved; the requisition will state which brand should be ordered. If a program participant calls the pharmacy for an infant formula order, please direct them to the Infant Formula Program Coordinator for their orders.
- 2. If the program participant shares that their baby does not tolerate the formula brand, please ask them to contact the Infant Formula Program Coordinator or the Dietitian.
- 3. Please order the formula as requested as soon as the requisition is received so it can arrive within 1-3 days.
- 4. Set aside the formula for the participant when it arrives and call them to inform them that their order is ready for pick-up.
- 5. When the participant comes to pick up the formula, please provide them with their order. Participants are to pick up infant formula directly from the pharmacy department rather than from the store shelves/aisles, unless instructed otherwise.
- 6. The program participant is not involved with payment processing. Charge the corporate credit card (details are on the requisition) with the amount charged by your supplier along with the 5% mark up above the acquisition cost.
- 7. Fax a receipt back to the Infant Formula Program Coordinator at the number listed below. Receipts are required for balancing requisitions each month. If we have not received the receipt, we will need to call your pharmacy to request it. The VISA may be reconciled up to 1½ months after, so we recommend keeping a copy of the receipt for at least 2 months.
- 8. We recommend keeping a file called the "Infant Formula Program" to keep requisitions and receipts for transactions.
- 9. It helps to familiarize pharmacy staff with the program so they can be aware of the program details in case questions arise from the participants or the Infant Formula Program Coordinator.

Your ongoing support is very important to the success of this program and is always greatly appreciated.

Thank you,

Infant Formula Program Coordinator

Phone:

Fax:

Note: Infant Formula Program Coordinator keeps 1 copy and sends 1 copy to pharmacy.

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## Appendix D Infant Formula Requisition Form

Date:				Administered by: Saskatchewan Prevention Institute
To:				1319 Colony Street
			<del></del>	Saskatoon, SK S7N 2Z1 306-651-4300
<del></del>		<del></del>	<del></del>	
	_	ddress and phone numb	er)	
ATTN:				
		(Name)		
Infant Form	ula Program Coordina	tor		
Phone:		<del></del>		
Fax:				
PLEASE ORDER FORM	/IULA AS SOON AS RE	QUISITION IS RECEIVED.		
Name of Client:				
Please call		at	_ when order is ready	for pick-up.
	(Name)	(Phone Number)		
Type of Formula:				
Amount: cases	s of concentrated liqu	iid; number of cases X an	nount per case =	. <u></u>
Billing Information:	VISA Card Number:		EXP:	
	Name on Card:			
Please send conv of r	eceint by fax to Infan	t Formula Program Coord	dinator at	
Trease seria copy or r	cecipt by tax to intain	eromala rrogram cook	(Fax Nu	mber)
Thank you for agree	ing to participate in	the Ministry of Health f	unded program to p	rovide infant formula to families
		-		nce a month. Your ongoing
support is greatly ap	preciated.			
Signed:				
Name:				

Note: Infant Formula Program Coordinator keeps 1 copy and sends 1 copy to pharmacy.

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## Appendix E Participant Information Sheet

You have been enrolled in the Saskatchewan Infant Formula Program. Infant formula will be ordered and available for pick-up at the following pharmacy:

Pnarmacy:	<del></del>
Address:	
Phone Number:	
Type of Formula:	
How the SK Infant Formula Program Works	
of formula at a time unless other arrangements have b	ant Formula Program Coordinator. The order will be for 4 cases been made. The SK Infant Formula Program will supply formula b 48 cases of formula over a 12-month period. All formula will
Reordering Formula: Call the Infant Formula Program Coordinator when you enough time for your formula to be ordered and arrive	u open your last case of formula. This will ensure there is e so that you do not run out.
	rtment. Please do not pick up formula from the store shelves or vance through the Infant Formula Program Coordinator.
Questions/Concerns: Infant Formula Program Coordinator – Contact to reor order, if your phone number or address changes, or you	rder formula if you have questions or concerns about your ou wish to change pharmacies.
<u>Dietitian</u> – Contact if you have any questions about mababy, as well as if you are concerned your baby is havi	aking formula, feeding your baby, or introducing food to youring a bad reaction to the formula.
Infant Formula Program Coordinator	Dietician
Name:	Name:
Phone:	Phone:
Fax:	

Note: Infant Formula Program Coordinator keeps 1 copy and provides 1 copy to client

## Appendix F Example of Tracking Form

APRIL 1, 20\_\_\_\_\_ TO MARCH 31, 20 \_\_\_\_\_ Do not send shaded cells - for your record only

Patient Last Name	Patient First Name	Patient HSN	Infant HSN	Patient Age	(yes/		Formula Start Date	Projected End Date	HR of Patient Residence	Accessing	Formula Brand/ Type	Quantity Sent to Date (in cases)	Graduated	Survey Sent	Left program early (provide date & explain why)	Transferred to Another Region (provide date and region)	Additional Info
	·																

**Note:** Infant Formula Program Coordinators submit this de-identified form annually to the Saskatchewan Prevention Institute via fax: 306-651-4301 or email: <a href="mailto:contact@skhiv.ca">contact@skhiv.ca</a>.

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# Appendix G Example of Roll-up of Provincial Statistics

FORMER HEALTH REGION (INSERT FISCAL YEAR)	Q1 Apr-Jun	Q2 Jul-Sep	Q3 Oct-Dec	Q4 Jan-Mar	(Insert Fiscal Year) Total
# patients enrolled					0
# infants enrolled					0
quantity of formula (cases)					0
# Status					0
# Non-Status					0
# on reserve					0
# off reserve					0

**Note:** Infant Formula Program Coordinators will compile quarterly reports into this form.