MEDICATION MANAGEMENT
Policy/Procedure

TITLE:	Application of Non-Prescription Topical Anesthetics	**NUMBER:**	20.77
Sponsor:	Director – Children's Surgical, Emergency, and Rehabilitation Services Drugs & Therapeutics	Page:	1 of 10
Approved by:	Medical Advisory Committee	Approval Date: Effective Date:	September 7, 2021 September 7, 2021
Applies To:	Clinical Programs, Registered Nurses, Licensed Practical Nurses, Medical Radiation Technologists, Anesthesia Assistants, Pharmacists		

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PREAMBLE

All patients at the IWK have the right to receive optimal pain management. All care providers should do what they can to minimize procedural pain in the provision of safe and compassionate care, as per the IWK's Comfort Promise (see Appendix A). Pain is an "unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (International Association for the Study of Pain, 2020).

The IWK provides a multitude of services to infants, children, youth, and women, including procedures such as but not limited to: venipuncture, immunizations, peripheral intravenous device (IV) insertion, and insertion/accessing of central venous access devices (CVADs). These interventions are painful and can be stressful for the patient and family. Topical anesthetic can reduce the pain associated with these procedures. A discussion with the

patient and family about options for non-prescription topical anesthetic prior to invasive procedures will support the most appropriate plan in each individual situation. Other options such as comfort positioning, sucrose (age appropriate) or distraction are other alternatives will also be offered.

The topical anesthetics contained within this policy are non-prescription products and have minimal risk. This policy is not inclusive of the intradermal injection of lidocaine. The care within this policy falls within the scope of practice for registered nurses (RNs), licensed practical nurses (LPNs), medical radiation technologists (MRTs), anesthesia assistants (AA) and pharmacists.

The purpose of this policy is to provide RNs, LPNs, MRTs, AAs and pharmacists with consistent direction and guidance in the use/application of topical anesthetics to infants, children, youth, and women, prior to invasive procedures. Each clinical area at IWK Health will determine the appropriateness of implementing this policy based on the area's patient population and context of practice.

POLICY STATEMENTS

1. RNs, LPNs, AAs and pharmacists have the authority to apply Ametop® (Tetracaine 4% Gel) and EMLA® (Eutectic Mixture of Local Anesthetic) without a patient-specific written order for inpatients and outpatients, for the purpose of dermal analgesia prior to a painful procedure. MRTs have the authority to apply Ametop® (Tetracaine 4% Gel) without a patient-specific written order for outpatients greater than 1 month of age who do not meet exclusion criteria (see policy statement 3 below).

2. **Inclusion Criteria**
   Infants, children, youth, and women who require **non-urgent*** painful procedures:
   - IV insertion,
   - venipuncture,
   - intramuscular (IM) and/or subcutaneous injections,
   - lumbar puncture,
   - bone marrow aspiration,
   - port-a-cath access,
   - joint injections

> **Please Note**
> Topical anesthesia has been shown to be ineffective for finger pricks and heel-sticks.

* Local anesthetic cream is not appropriate if the painful procedure is urgent (less than 30 minutes). Application of topical local anesthetic should not delay urgent treatment(s)

3. The following circumstances require further collaboration with the most responsible physician/approved prescriber prior to application of a topical anesthetic:

   - Open areas of the skin
     - For information on pain management for uncomplicated laceration repair, refer to Policy 1355 - Care Directive for the Application of Lidocaine, EPINEPHrine

and Tetracaine Gel by Registered Nurses on Patients Requiring Laceration Repair in the Emergency Department

- A known sensitivity to Ametop® or EMLA®
- Hypersensitivity to local anesthetics
- Renal impairment
- Hepatic disease
- Known G6PD deficiency, congenital or idiopathic methemoglobinemia
- Use of Ametop® in premature neonates less than 1 month corrected age and term neonates less than 1 month post-natal age (see note below)
- Infants less than 1 month receiving repeated doses of methemoglobin-inducing drugs: (e.g. acetaminophen, acetanilid, aniline dyes, benzocaine, chloroquine, dapsone, naphthalene, nitrates and nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, sulfonamides and quinine)

In these circumstances, **a written order is required**. The discussion should also include other approaches to manage the pain associated with invasive procedures when unable to receive Ametop® or EMLA®

Please Note
The use of Ametop® in premature neonates less than 1 month corrected age and term neonates less than 1 month post-natal age is relatively contraindicated and requires consultation with a prescriber and a written order prior to use**.** EMLA® may be used in these patients as outlined in this policy without consulting the prescriber.

4. Adherence to maximum doses, application times and surface areas is critical to avoid serious side effects (refer to IWK Drug Dosing Guidelines). Application beyond the recommended maximum doses requires prescriber approval and a written order

5. Topical local anesthetics may be applied to a maximum of four (4) sites concurrently (e.g., dorsa of both hands, antecubital fossae prior to intravenous initiation)

6. Always assess the need for adjunct pain management and anesthetic for deeper procedures; Ametop® and EMLA® only provide superficial anesthesia

Please Note
Although topical anesthetics are helpful in reducing pain from the needle breaking the skin with intramuscular (IM), subcutaneous or joint injections, they are not effective in reducing pain from the treatment itself. Patients and families should be aware of what to expect.

7. Assessment of pain post-procedure/intervention will be performed using a recognized pain scale as per Policy 1519 - Pain Management Policy. This assessment will be recorded on the patient's permanent health record

8. The health care provider who applies topical anesthetic must be familiar with all adverse effects of the topical anesthetic and actions to take should a severe adverse reaction

occur, including but not limited to immediate removal of the topical anesthetic (rinse with water) and notification of the physician

Please Note
Local reactions to Ametop® (erythema, induration, pruritis) and EMLA® (blanching) are common and expected based on their vasoactive properties (see Appendix B). The affected area should be clearly defined and limited to the area of application. Adverse reactions include blistering (Ametop®) and methemoglobinemia (EMLA®). Allergic reactions may present as an allergic contact dermatitis, which is usually delayed rather than immediate, and anaphylaxis, of which signs and symptoms include urticaria (hives) and/or systemic involvement (e.g. angioedema, bronchospasm, etc.). In cases where a local erythematous reaction may impair the ability to appropriately monitor the injection site (e.g. immediate injection-site reactions to immunizations), EMLA may be considered.

9. In the event of a serious adverse drug reaction (ADR), follow Policy 339 – Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents (Vanessa's Law)

GUIDING PRINCIPLES AND VALUES

- The IWK's implementation of the Comfort Promise promotes the use of four strategies: use of topical anesthetics, sucrose or breastfeeding for infants 0-12 months, comfort positioning and/or developmentally appropriate distraction
- Topical anesthetics can be applied painlessly prior to procedures to help minimize anxiety, the potential stress response of anticipated pain and potential long term sequelae
- Non-pharmacological interventions (e.g. distraction, comfort positioning, behavioral techniques, skin-to-skin, breastfeeding, sucrose, etc.) are an essential part of minimizing procedural pain and enhancing the benefit of topical anesthesia

PROCEDURE

1. Collaborate with patient/Substitution Decision Maker (SDM) regarding plan of care. Based on assessment, and informed by the patient/SDM, prepare the patient based on developmental level and determine the need for procedural support such as distraction, as well as the need for an assistant to support the safe completion of the procedure while minimizing the risk of pain and distress. Consults to Child Life or Anesthesia may be required

2. Determine appropriate comfort measures for the procedure, e.g. use of topical anesthetics, sucrose or breastfeeding for infants 0-12 months, comfort positioning and/or developmentally appropriate distraction

3. Determine if the patient has any contraindications to topical anesthetic or adhesives, or previous negative experiences with medical interventions

Please Note
Ametop® is generally the agent of choice for infants and children greater than one month of age. It has a faster onset of action and is vasodilatory, making it preferred for venipuncture. EMLA® is used in premature neonates less than 1 month corrected age and term neonates less than 1 month post-natal age.

4. Refer to the IWK Drug Dosing Guidelines prior to application for recommended amounts, surface areas and application times

5. Obtain verbal consent from the patient/SDM prior to application of the topical anesthetic

6. Placement of a topical anesthetic should be as follows:
   - Venipuncture or IV insertion: over sites with either a visible or palpable vein (e.g. dorsa of both hands, antecubital fossae)
   - IM or subcutaneous injections: over age-appropriate injection site(s)
   - Lumbar puncture: over the site identified, usually L3-4, or L4-5
   - Bone marrow aspiration: over the posterior iliac crest ,unless otherwise indicated by the physician
   - Port-a-cath access: over the port access area
   - Joint injection: over joints identified by the physician for injection

7. Avoid broken or irritated skin, mucous membranes, genitals, as well as eyes, ears, and mouth. A greater rate and extent of absorption has been observed in patients with atopic dermatitis

8. Clean application site with a hospital approved antiseptic. Apply a thick layer of the anesthetic cream topically to the site(s). **Do not rub**

9. Place an occlusive dressing over the topical anesthetic covering the potential site(s) to keep the product in place and prevent accidental ingestion (e.g. Tegaderm®, Opsite®, Microfoam®)

10. Document the application of the topical anesthetic on the permanent health record noting time and location, site(s) of application, and dose (amount) as applicable

11. Following administration, avoid scratching or exposing the area to extreme temperatures; the patient will be unable to feel pain at the site

12. Apply Ametop® for at least 30 minutes or EMLA® for at least 60 minutes prior to the painful procedure

13. Monitor the application site for a reaction and document on the permanent health record should any reaction occur. Adverse effects should be reported as per IWK Policy 540: Patient Alerts (Allergies-Adverse Reactions-Cautions)

14. Once the topical anesthetic has been applied to the skin for the allotted time, remove the dressing and thoroughly wipe the area of any excess topical anesthetic

Please Note
If the procedure has not occurred, Ametop® must be removed after 2 hours, although removal after the minimum application time (30-45 minutes) is strongly recommended to reduce the risk of erythema. EMLA® may be left in place for up to 5 hours depending on age (see IWK Drug Dosing Guidelines). Analgesia persists after removal (see Appendix B), therefore reapplication should only be considered beyond the duration of effect and within the maximum dosing guidelines

15. Document the removal on the permanent health record

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RELATED DOCUMENTS

Policies:

Policy 20.05 – Administration of Medication
Policy 10.11 – 24 Hour Medication Administration Record (cMAR)
Policy 124.0- Consent to Treatment
Policy 1519 - Pain Management
Policy 339 – Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents (Vanessa's Law)
Care Directive 1355- Care Directive for the Application of Lidocaine, Epinephrine and Tetracaine Gel by Registered Nurses on Patients Requiring Laceration Repair in the Emergency Department
Care Directive 1330 –Care Directive for the Investigation of Febrile Infants (0-90 days) by Registered Nurses in the Emergency Department

APPENDICES

Appendix A – Definitions
Appendix B- Topical Anesthetic - EMLA® and Ametop® Product Comparison

APPENDIX A

Definitions

Comfort Promise – IWK Health is making a promise to do everything we can to reduce needle poke pain in our patients by implementing a hospital-wide initiative called Comfort Promise. All patients will be offered four pain management techniques to prevent and minimize needle-poke pain- comfort positioning, distraction, sucrose or topical analgesic

Pain - An "unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (International Association for the Study of Pain, 2020)

Non-prescription products - Medications available for sale to patients without an approved prescriber's prescription. These medications are scheduled by NAPRA (National Association of Pharmacy Regulatory Authorities) as Schedule 2, 3 or unscheduled. This means these medications pose minimal risk and are appropriate for patients to self-select

Substitute Decision Maker (or "SDM") - The person who will give consent on behalf of the patient if the patient does not have the capacity to consent. Refer to Policy 124.0 - Consent for Treatment for more specific details

APPENDIX B

Topical Anesthetic - EMLA® and Ametop®
Product Comparison

	EMLA® cream (lidocaine 2.5%+ prilocaine 2.5%)	**Ametop® gel [4% amethocaine (tetracaine)]**
Supplied	5 g tube (multiple use)	1.5 g tube (single use)
Storage	Room temperature	Refrigerated
Onset	60 minutes	30 minutes for venipuncture 45 minutes for IV catheter insertion
Maximum Application Time	Age-based (refer to IWK Drug Dosing Guidelines)	Recommended 30 to 45 minutes Maximum 2 hours
Maximum Daily Dose	Refer to IWK Drug Dosing Guidelines	Refer to IWK Drug Dosing Guidelines
Duration of Effect	1-2 hours after removal	4-6 hours after removal
Adverse Effects	Frequent: **pallor, blanching** of the area Occasional: erythema Rare: edema, itching, hypersensitivity, methemoglobinemia	Frequent: **erythema** of the area Occasional: itching, slight edema Rare: blister formation, hypersensitivity
Advantages	- Vasoconstrictive – may be helpful for patients with bleeding disorders or using anticoagulants - May be used before immunizations (may be preferred) - No cross-sensitivity with Ametop®	- Rapid onset - useful where urgent venipuncture is required (preferred product in the pediatric OR, ED and PICU**)** - Vasodilatory (preferred for venipuncture) - May be used before immunizations - No cross-sensitivity with lidocaine
Disadvantages	- Methemoglobinemina (rare – has been used safely in premature infants) - Slower onset (60 minutes)	- Limited data in pre-term neonates and neonates less than 1 month - Sensitization can occur with repeated/frequent use

Adapted from BC Children's Hospital COMPARISON TABLE OF AMETOP GEL, EMLA CREAM AND PAIN EASE SPRAY (2012) and Canadian Pediatric Society Position Statement - Managing pain and distress in children undergoing brief diagnostic and therapeutic procedures (Paediatr Child Health 2019 24(8):509-521).

IWK Policies Being Replaced

(Please List)

Version History

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)