

APPLICATION TO WIDEN THE CLASSIFICATION FOR ARTICHAINE, LIGNOCAINE, AND  
PRILOCAINE WITH OR WITHOUT FELYPRESSIN TO ALLOW ORAL HEALTH  
THERAPISTS REGISTERED WITH THE DENTAL COUNCIL TO USE THEM IN THEIR  
PRACTICE

## EXECUTIVE SUMMARY

This application proposes extending the availability of selected local anaesthetics with or without felypressin (a vasoconstrictor) for use by oral health therapists. This is in line with the current use by dental therapists in children up to 18 years of age.

From 1 November 2017, the Dental Council will have oral health therapists registered with their own scope of practice. This new category of dental practitioners is a reflection of the three-year university degree programme (first offered in 2006), which has replaced the dental hygiene and dental therapy qualifications previously available. Oral health therapists currently register and practise as a dental hygienist and/or dental therapist. Consequently, these practitioners are already regulated and practise within the health system of New Zealand. Oral health therapists receive education in use of local anaesthetics—including indications, contraindications, precautions, adverse events, and when to refer to a dentist.

Until the new Oral Health Therapist category is available, oral health graduates register as dental hygienists and/or dental therapists. If registering as a dental therapist, they can administer local anaesthetic on children up to 18 years of age without any direct supervision by a dentist, or dentist on-site. If registering as a dental hygienist and not a dental therapist, the same graduate can only administer local anaesthetic when a dentist is on the premises. This limitation affects both the oral health therapist and the dentist. It also potentially can fragment therapy unnecessarily, add to discomfort of patients (as a local anaesthetic may not be used when it ideally would be), be less convenient for patients (by requiring unnecessary referral or rescheduling for part of the work) and limits the work oral health therapists can do outside of a dental practice (e.g. in residential care facilities or mobile units).

The scope of practice for the new oral health therapist has been widely consulted on and will be in place 1 November 2017. This scope includes the ability for oral health therapists to use selected local anaesthetics (with or without vasoconstrictors) without needing a dentist to be on-site. The request for a change in classification status enables this to occur.

The local anaesthetics affected, prilocaine, lidocaine (lignocaine) and articaine, are amide-type anaesthetics, which have low likelihood of allergy, and are relatively short-acting. Local anaesthetics (LAs) are widely used by a range of dental practitioners (dentists and dental specialists, dental therapists, and dental hygienists), with low incidence of adverse events. They have been used in many different countries by dental practitioners for many years, with an estimated 300 million doses given per year by dental practitioners in the United States.<sup>1</sup> Felypressin is a vasoconstrictor that has also commonly been used in dentistry combined with local anaesthetic.

Contraindications and precautions for these medicines are small in number and can be ascertained through the medical history.

Oral health therapists have appropriate education for this role. They do the same resuscitation courses as dentists do, on a two-yearly basis. All dental practitioners using local anaesthetics draw back the syringe before administration to ensure the injection is not inadvertently given into a blood vessel, therefore minimising systemic exposure.

The risk-benefit of this minor change to the classification statement is reasonable.

## PART A

### 1. International Non-proprietary Name of the medicine

Lidocaine (INN and BAN) also known as lignocaine, including in the classification schedules

Prilocaine

Articaine

Felypressin

### 2. Proprietary name (s)

**Table 1: Proprietary injectables including these active ingredients primarily used for dental reasons**

Medicine	Brand	Company
Prilocaine plus felypressin	Citanest® dental with Octapressin® solution for injection (3% prilocaine, felypressin 0.54 µg/mL)	Dentsply
Lidocaine and adrenaline	2% Xylocaine® Dental with Adrenaline 1:80,000 Solution for injection, dental cartridge	Dentsply
Lidocaine and adrenaline	Xylestesin-A® 20 mg/mL + 12.5 µg/mL solution for injection (for dentistry)	3M
Articaine and adrenaline	Ardanest articaine 4% with adrenaline 1:100,000; Ardanest articaine 4% with adrenaline 1:200,000	HealthCare Essentials Ltd
Articaine and adrenaline	Septanest articaine 4% with adrenaline 1:100,000	Ivoclar Vivadent
Articaine and adrenaline	Ubistesin Forte articaine 4% with adrenaline 1:100,000; Ubistesin articaine 4% with adrenaline 1:200,000	3M
Lignocaine and adrenaline	Lignospan 2% with adrenaline 1:80,000	Ivoclar Vivadent

**Table 2 Proprietary injectables including these active ingredients that are not specific for dentistry**

Medicine	Brand	Company
Lidocaine	Xylocaine 1%, and Xylocaine 2%	Pharmacy Retailing
Lidocaine with adrenaline	Xylocaine 2% with Adrenaline 1:100,000 and Xylocaine 2% with Adrenaline 1:200,000	Pharmacy Retailing
Lidocaine	Lidocaine-Clarix solution for injection (1% and 2% lidocaine)	Multichem
Prilocaine	Citanest® 0.5% or 2.0%	Pharmacy Retailing

NB Formulations of the selected local anaesthetics with adrenaline will be captured by the classification change because adrenaline is general sales in medicines for injection containing 0.02% or less. 1:80,000 is equivalent to 0.00125%.

As this application relates to use of injectables in dentistry, other products containing these ingredients, e.g. topical creams, have not been listed as they will not be affected.

Dentists mostly use cartridges for local anaesthetic administration, with limited other injectable forms used in practice.

### **3. Name of company/organisation/individual requesting reclassification**

Dental Council - New Zealand.

The Dental Council is a responsible authority created by the Health Practitioners Competence Assurance Act 2003 to regulate the oral health professions. It ensures oral health practitioners meet and maintain its standards in order to protect the health and safety of the New Zealand public. The oral health practitioners it regulates are dentists, dental specialists, dental therapists, dental hygienists, clinical dental technicians, dental technicians, and orthodontic auxiliaries. From 1 November 2017 it will also regulate oral health therapists.

### **4. Dose form(s) and strengths for which a change is sought**

Dose form: Injection

Strength is not specified, consistent with the current classification entries.

## 5. Pack size and other qualifications

There are no qualifications required on pack size. We propose adding the qualification that the medicine can be used by an oral health therapist registered with the Dental Council.

## 6. Indications for which change is sought

Local anaesthetic agents: articaine, prilocaine, lidocaine (lignocaine), used for local anaesthesia.

NB: as lidocaine is the INN name, it is used throughout this application rather than lignocaine. It is noted that in the classification statement on the Medsafe website, a lidocaine search is referred to the lignocaine entry. Data sheets typically refer to lidocaine.

Felypressin: Localising agent (vasoconstrictor) as an adjunct to local anaesthesia.

Licensed indication wording varies across the products, e.g. Citanest with octapressin has the following indications:

- Infiltration anaesthesia in dentistry, where there is no need for profound ischaemia in the injected area.
- Regional nerve block anaesthesia in dentistry.

Xylocaine 2% with adrenaline states the following:

Lignocaine solutions are indicated for the production of local nerve anaesthesia in routine dental procedures and oral surgery by means of infiltration and nerve block techniques. Lignocaine solutions with adrenaline are recommended for oral surgery requiring prolonged duration of anaesthesia and haemostasis.

## 7. Present classification of medicines

**Table 3 Current classifications of medicines**

Medicine	Current Classification
Articaine	Prescription <b>except</b> when used as a local anaesthetic in practice by a dental therapist registered with the Dental Council
Prilocaine	Prescription except when used as a local anaesthetic in practice by a dental therapist registered with the Dental Council; <b>except</b> when specified elsewhere in this schedule  Pharmacy only: for dermal use in medicines containing 10% or less of local anaesthetic substances

Lidocaine	<p>Prescription: for injection <b>except</b> when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatry Board or dental therapist registered with the Dental Council; for oral use; for ophthalmic use <b>except</b> when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; <b>except</b> when specified elsewhere in this schedule; <b>except</b> for external use and in throat sprays in medicines containing 2% or less; in throat lozenges in medicines containing 30 milligrams or less per dose form</p> <p>General sale: for external use and in throat sprays in medicines containing 2% or less; in throat lozenges in medicines containing 30 milligrams or less per dose form</p> <p>Pharmacy only: for urethral use; for external use in medicines containing 10% or less and more than 2%</p>
Felypressin	<p>Prescription: <b>except</b> when combined with a local anaesthetic and used in practice by a dental therapist registered with the Dental Council</p>

8. Classification sought

Table 4 Proposed classifications of medicines (red shows the proposed changes)

Medicine	Proposed Classification or comments
Articaine	<p>Prescription <b>except</b> when used as a local anaesthetic in practice by a dental therapist <b>or oral health therapist</b> registered with the Dental Council</p>
Prilocaine	<p>Prescription <b>except</b> when used as a local anaesthetic in practice by a dental therapist <b>or oral health therapist</b> registered with the Dental Council; <b>except</b> when specified elsewhere in this schedule</p> <p>Pharmacy only: for dermal use in medicines containing 10% or less of local anaesthetic substances</p>
Lidocaine	<p>Prescription: for injection <b>except</b> when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatry Board or dental therapist <b>or oral health therapist</b> registered with the Dental Council; for oral use; for ophthalmic use <b>except</b> when used in</p>

	<p>practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; <b>except</b> when specified elsewhere in this schedule; <b>except</b> for external use and in throat sprays in medicines containing 2% or less; in throat lozenges in medicines containing 30 milligrams or less per dose form</p> <p>General sale: for external use and in throat sprays in medicines containing 2% or less; in throat lozenges in medicines containing 30 milligrams or less per dose form</p> <p>Pharmacy only: for urethral use; for external use in medicines containing 10% or less and more than 2%</p>
Felypressin	Prescription: <b>except</b> when combined with a local anaesthetic and used in practice by a dental therapist or <b>oral health therapist</b> registered with the Dental Council

## 9. Classification status in other countries (especially Australia, UK, USA, Canada)

The classification status for these injectable agents is provided in Table 5. New Zealand varies from other countries in using the classification statement to allow different medicines to be used by various health practitioners. Hence, other countries typically have prescription-only status for these medicines. However, the UK and Australia both allow use of local anaesthetics by dental therapists and dental hygienists without direct supervision by a dentist, similar to what we are proposing to enable through this classification change. In Australia an oral health therapist can also do this without direct supervision, but the UK does not have this category of practitioner. See Appendix 1 for further detail on other countries.

**Table 5 Classification Status in Australia, UK, Canada and USA**

Medicine	Australia	UK	Canada	USA
Lidocaine injection	Prescription	Prescription	Schedule 2 (pharmacist-only) for parenteral use	Prescription
Articaine injection	Prescription	Prescription	No listing in the schedule	Prescription
Prilocaine injection	Prescription	Prescription	Schedule 2 (pharmacist-only) for parenteral use	Prescription
Felypressin injection	Prescription	Prescription	No listing in the schedule	Not found

NB: Classifications for non-injectable forms can vary but are excluded as they are not relevant to this application.

**10. Extent of usage in New Zealand and elsewhere (e.g. sales volumes) and dates of original consent to distribute**

These medicines have extensive use in the dental industry and in non-dental surgical procedures.

Sales data is not readily available, but some companies may choose to confidentially make this information available to the Medicines Classification Committee. [REDACTED]

[REDACTED]

**11. Labelling or draft labelling for the proposed new presentation(s)**

Not applicable. The labelling would not need any update.

**12. Proposed warning statements if applicable**

There would be no need for any additional warning statements as usage is virtually unchanged.

**13. Other products containing the same ingredient(s) and which would be affected by the proposed change**

The products listed in Table 6 (below) have Medsafe datasheets available.

**Table 6. Products affected by the proposed changes**

Medicine	Brand	Company
Prilocaine plus felypressin	Citanest® dental with Octapressin® solution for injection (3% prilocaine, felypressin 0.54 µg/mL)	Dentsply
Lidocaine and adrenaline	2% Xylocaine® Dental with Adrenaline 1:80,000 Solution for injection, dental cartridge	Dentsply
Lidocaine and adrenaline	Xylestesin-A® 20 mg/mL + 12.5 µg/mL solution for injection (for dentistry)	3M
Articaine and adrenaline	Ardanest articaine 4% with adrenaline 1:100,000; Ardanest articaine 4% with adrenaline 1:200,000	HealthCare Essentials Ltd

Articaine and adrenaline	Septanest articaine 4% with adrenaline 1:100,000	Ivoclar Vivadent
Articaine and adrenaline	Ubistesin Forte articaine 4% with adrenaline 1:100,000; Ubistesin articaine 4% with adrenaline 1:200,000	3M
<b>Non Dental</b>		
Lidocaine	Xylocaine 1%, and Xylocaine 2%	Pharmacy Retailing
Lidocaine with adrenaline	Xylocaine 2% with Adrenaline 1:100,000 and Xylocaine 2% with Adrenaline 1:200,000	Pharmacy Retailing
Lidocaine	Lidocaine-Clarix solution for injection (1% and 2% lidocaine)	Multichem
Prilocaine	Citanest® 0.5% or 2.0%	Pharmacy Retailing

## PART B

### **Reasons for requesting classification change including benefit-risk analysis**

There is a favourable benefit-risk analysis for this minor change in classification.

This proposal will aid oral health therapists to work to their competencies without needing standing orders that will have no greater safety and increase the bureaucracy. It will mean that they can continue to practise within their full scope without supervision by a dentist. When attending patients at residential care or other facilities, they will be able to treat the patient as appropriate for their scope of practice, and not need to refer some care that is within their scope to a dentist unnecessarily.

Patient convenience arises from the increased likelihood of having all the care able to be provided in the one visit, rather than rebooking for part of the care with a risk of non-return. A patient will be able to have a local anaesthetic administered rather than having to suffer from excessive pain to have all the necessary treatment at the time. There may be a saving to society in having oral health therapists able to work to their scope of practice rather than requiring a dentist present for work that is within the oral health therapist's scope, or risking further deterioration in the condition and a more costly procedure being required by delaying some of the treatment unnecessarily.

The risks have been managed by: appropriate undergraduate training; requiring practitioners to undertake resuscitation training every two years; and use of medicines that are very safe in small doses and a localised manner when used in dental work. The history of dental therapists administering local anaesthetics in their work for decades without needing a dentist's supervision gives confidence in this expansion to oral health therapists who have had even more training.

Below we provide background information on oral health therapists, dental therapists and dental hygienists, their use of local anaesthetics, and the work done by the Dental Council in this area. Then we provide further information about the benefit-risk analysis.

#### BACKGROUND ON DEVELOPMENT OF ORAL HEALTH THERAPY SCOPE OF PRACTICE

New Zealand was a leader in establishing the role of dental therapists, with school 'dental nurses' first introduced in NZ in 1923.<sup>3</sup> Initially they provided dental prophylaxis, restorations, and extraction of primary teeth. Now called dental therapists, their work includes an extensive range of preventive and restorative services, and thus they frequently use local anaesthetics.

Internationally there is a move for dental therapists to undergo university degree-level education and to expand to treating adults.<sup>3</sup> Nash et al<sup>3</sup> reported that studies in Canada and Australia have shown good quality of work, and for Canada "there have been no reports of serious injuries or record of litigation or malpractice claims against dental nurses over the 50 years of their existence".

In New Zealand, oral health therapy is a relatively new practice, integrating the previous educational programmes of dental hygiene and dental therapy. The introduction of a three-year, tertiary level oral health degree, combining the previous dental hygiene and dental therapy programmes, marked a significant shift in the oral health workforce. Auckland University of Technology (AUT) introduced the new oral health programme in 2006, followed by the University of Otago in 2007. Oral health

graduates currently register with the Dental Council in either the dental therapy and/or dental hygiene scope of practice.

There are no longer any standalone educational programmes for dental hygiene or dental therapy offered in New Zealand. The effect of the change in the university programmes is that, since 2007/08, there have been no new New Zealand educated dental hygienist or dental therapist graduates—only ‘oral health therapists’. This means that, over time, the number of dental hygienists and dental therapists will dwindle.

The Council believes that the oral health therapy scope of practice more accurately describes the oral health graduates’ full set of capabilities and breadth of the new qualification, and recognises these practitioners as a new profession within the oral health sector.

The Dental Council currently has around 440 oral health therapy graduates on its register, with an additional 77 graduates from 2016 who are eligible to register as an oral health therapist.

The Council gazetted the oral health therapy scope of practice on 3 November 2016 ([2016-gs6131](#)), for coming into effect on 1 November 2017.

#### ADMINISTRATION OF LOCAL ANAESTHETICS BY ORAL HEALTH THERAPISTS

The Dental Council consulted twice<sup>1</sup> with its stakeholders on the establishment and details of the oral health therapy scope of practice, including on the capabilities of oral health graduates to administer local anaesthetics, and the appropriate level of supervision to perform this task.

Currently, oral health graduates can administer local anaesthetics under the dental hygiene scope of practice (requires direct clinical supervision—dentist onsite) to patients of all ages; while the dental therapy scope of practice allows administration of local anaesthetics to patients up to 18 years of age—without the requirement for supervision.

Mapping of the competency standards and performance measures for dental hygiene, dental therapy and dentistry against the curricula of the oral health and dental programmes at the University of Otago and the AUT BHSc in Oral Health programme, illustrated that the same competencies are achieved for the administration of local anaesthetics by both dental and oral health graduates. Oral health graduates know of the restrictions<sup>2</sup>, potential interactions with medications, complications associated with the administration of local anaesthetics, and the management of the patient in the unfortunate event of a medical emergency.

The different level of knowledge of physiology, human disease and pharmacology between the dental and oral health graduates was also illustrated, and was considered to have implications for the management of medically compromised patients. However, these implications are not limited solely to the administration of local anaesthetics—they relate to all clinical activities performed by an oral

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<sup>1</sup> The [first consultation](#) was in November 2014 following the conclusion of the working group investigation. A [follow-up consultation](#) was issued in March 2016, with amended proposals as a result of the feedback received during the first consultation. All registered oral health practitioners and other stakeholders (such as Ministry of Health, Health and Disability Commissioner, District Health Boards, professional associations etc) were included in both consultations. Hon Minister Peter Dunne has also been kept up to date with progress on this matter during its quarterly meetings with the Dental Council.

<sup>2</sup> Restricted to administering local anaesthetic using dentoalveolar infiltration and inferior dental nerve block techniques.

health therapist. Consequently, the expectation is that typically, and consistent with current practice, a treatment plan for a medically compromised patient would be discussed with a dentist or dental specialist before commencement of treatment, irrespective of the need, or not, for local anaesthetic. The oral health therapy scope of practice is practised within a consultative professional relationship with at least one dentist or dental specialist—with the stated purpose of providing professional advice in relation to the treatment and management of patients, when needed.

Based on the advice received from the two oral health programmes, the Dental Council is confident that oral health graduates are competent in providing local anaesthetic for their patients. The programme provides students with the necessary education and training to enable them to provide local anaesthetic for their patients competently, safely and appropriately. The majority of submitters to the two consultations agreed with this position.

In the event of a medical emergency related to the administration of local anaesthesia, oral health students receive resuscitation training at the same level as other oral health practitioners (excluding dental technicians, and dentists/dental specialists providing sedation). That is, NZRC CORE Immediate training (previously named CORE Level 4), or equivalent.

TYPE OF ORAL HEALTH THERAPY SCOPE OF PRACTICE ACTIVITIES WHERE LOCAL ANAESTHETICS COULD BE ADMINISTERED

***Removing hard and soft deposits from all tooth surfaces:*** use in selected cases for the removal of hard deposits, where appropriate. For example, deep scaling of root surfaces, sensitive teeth and/or inflamed gum tissue.

***Restorative activities for patients up to age 18:***

- ***Preparing cavities and restoring primary and permanent teeth using direct placement of dental materials***
- ***Extracting primary teeth***
- ***Performing pulpotomies on primary teeth***
- ***Preparing primary teeth for, and placing, stainless steel crowns.***

COMPETENCE NOTIFICATIONS RELATED TO THE ADMINISTRATION OF LOCAL ANAESTHETICS

A review of the Dental Council competence notifications for dental therapists and dental hygienists, shows few notifications for either and nothing that would indicate that the proposed change to the classification statement would lead to increased harm.

**1. A statement of the benefits to both the consumer and to the public expected from the proposed change**

Regular dental checks are needed to maintain health of teeth and gums. The NZ annual health survey 2014/2015<sup>4</sup> found that 48% of all adults with natural teeth had visited a dental health care worker in the past 12 months. People in more deprived areas, or people of Māori, Asian or Pacific ethnicity have

lower attendance than others. Most Pacific, Māori and Asian adults only visit for dental problems, not regular check-ups. Dental extraction for tooth decay, abscess, infection or gum disease was reported to have occurred in the last 12 months by at least 10% of Pacific and Māori adults. Dental extraction affects quality of life, and usually results from not seeking dental care (prevention or treatment) early.

Local anaesthetics are widely used by dentists, dental specialists, dental therapists and dental hygienists. They are very effective in reducing pain during dental procedures.<sup>5</sup> As dental anxiety reduces the likelihood of routine attendance at the dentist,<sup>6</sup> ensuring patient comfort is an important part of dental procedures. However, without the classification change there are some restrictions in usage by graduates of the oral health therapy degree courses.

Dental hygienists currently require a dentist to be on the premises if they are to give a local anaesthetic. They are not required to routinely check for every patient with the dentist before using the local anaesthetic, nor is the dentist required to be in the same room. This differs from dental therapists who can give a local anaesthetic when treating children and adolescents without needing a dentist on the premises. As the oral health graduates are able to give local anaesthetics to children without a dentist's supervision if they are registered as a dental therapist, it is inconsistent that they cannot do the same for adults.

The existing situation is disadvantageous for the public who may have to have their treatment disrupted or have less comfortable treatment. It is disadvantageous for dentists, many of whom report time pressure stress,<sup>7</sup> who may have to stay on-site unnecessarily. It is also unfortunate for the oral health graduate who may have increased juggling and time pressures from managing patients within the existing restriction. A patient who needs a local anaesthetic and is rebooked may not return for the remainder of their treatment, so risk poorer care, in addition to inconvenience. The alternative approach of having a standing order in place would provide no greater safety than currently exists and is more burdensome on dentists and oral health practitioners. The use of standing orders is not common in private dental practices. In the public sector, the scale of administration would be very difficult to manage effectively and safely, with approximately 500,000 children cared for under the community oral health services. The proposed change provides flexibility and aids quality care and patient convenience.

## **2. Potential risk of harm to the consumer as a result of the proposed change, and factors to mitigate this risk**

The proposed change is in line with the education and expertise of the graduates of the three-year oral health therapy degree courses from the University of Otago and Auckland University of Technology. The difference is that rather than dental therapists treating patients up to 18 years of age with a local anaesthetic without a dentist on-site, oral health therapists will not have an upper age limitation. Local anaesthetic overdose has less risk in adults than children.<sup>8</sup>

The local anaesthetics and vasoconstrictor chosen have good safety profiles. Amide local anaesthetics are safer than the earlier ester local anaesthetics such as procaine.<sup>8</sup> The local anaesthetics have short half-lives (e.g. 1-2 hours) and have lasting effects in the soft tissue of no more than 8 hours when used with a vasoconstrictor.<sup>8</sup> Felypressin has a better profile for interactions than adrenaline (see

interactions, below).<sup>9</sup> By including felypressin in the classification change, oral health therapists can use the vasoconstriction actions reducing the rate of absorption of the local anaesthetic, prolonging the duration of action and minimising systemic effects.<sup>8</sup> As the vasoconstrictor slows the systemic absorption, the body has plenty of time to eliminate the local anaesthetic from the body as it is absorbed.

Local anaesthetic agents and their excipients can rarely cause harm, as can the injection itself. Oral health therapists are well trained in their University degree course in local anaesthetics with or without vasoconstrictors. They work on a simulation model to perfect their technique, and also do a limited number of injections on each other before proceeding to administering local anaesthetics to patients as part of the treatment plan.

Having a dentist on-site, or not, is unlikely to have any effect on the injection technique used. Oral health therapists will be allowed by their scope of practice to use dentoalveolar infiltration and inferior dental nerve block techniques for the administration of local anaesthetics. These practitioners are already administering local anaesthetic injections without dentists on site (dental therapists) or in the same room (dental hygienists), so there will be no greater risk of harm under the proposed classification change.

Intravascular injections may result in systemic reactions and need to be avoided. This is done across dentistry by the practice of aspiration (pulling back the syringe to ensure a blood vessel has not inadvertently been struck) prior to administering the injection. Syringe devices are used to aid aspiration, as in Figure 1. This standard practice would not change under the changing classification.

**Figure 1: Syringe device and cartridges for injection (needle not shown)**



Registered oral health therapists will have received training on indications, contraindications and precautions to local anaesthetic and vasoconstrictor use. They will be asking patients about relevant medical history, and in the case of a higher patient risk, they will consult with the dentist/dental specialist before proceeding with the treatment, or refer if required. Similar professional judgment is required in all other areas of oral health therapy practice.

In the event of a medical emergency related to the administration of local anaesthesia, oral health students receive resuscitation training at the same level as other oral health practitioners. That is,

NZRC CORE Immediate training (previously named CORE Level 4), or equivalent. This is required to be maintained following graduation, with the Dental Council requiring resuscitation training to the same level, every two years. Oral health practitioners declare compliance with this obligation as part of their annual practising renewal. Some first aid providers cater courses to dental practitioners with all of the dental practitioners doing these courses together.

Like dental therapists and dentists, oral health therapists will need to have oxygen available when treating patients. Unlike the requirement for dentists, but in line with dental therapists, there is no requirement for adrenaline for oral health therapists. Dental therapists have been treating children up to 18 years of age with local anaesthetics for decades. There are 500,000 children aged 0-12 years currently treated by the school dental services in NZ. Another 250,000 are under the adolescent contracts, mostly with dentists.

### **3. Ease of self-diagnosis or diagnosis by the relevant health professional for the condition indicated**

Oral health therapists will be able to ascertain for which procedures or patients local anaesthetics would be appropriate, when not to administer a local anaesthetic, and when a local anaesthetic with or without vasoconstrictor is required, just as both dental hygienists and dental therapists do now.

### **4. Relevant comparative data for like compounds**

Oral health therapy is a new scope of practice coming into being from November 2017. There is no comparative data for like compounds for this application, except to note that dental therapists have had similar access to that proposed to the medicines concerned for some time.

### **5. Local data or special considerations relating to New Zealand**

NZ has had dental therapists (previously called dental nurses) treating children in school dental clinics since the 1920s.<sup>3</sup> They have used local anaesthetics for many decades in this practice. There is no requirement for them to have adrenaline on-site. They do have oxygen, and they have the requirement to train in resuscitation (CORE Immediate). What is proposed is very similar to the current arrangement, and recognises the competencies of oral health therapists.

The Dental Council has a practice standard for medical emergencies in dental practice (see appendix 3). This document requires dentists and other dental practitioners to remain up-to-date in resuscitation training with two-yearly training, and requires them to have written protocols for managing medical emergencies.<sup>10</sup> It includes anaphylaxis management. Dental therapists, dental hygienists (and oral health therapists when the scope comes into effect) are required to have an oxygen cylinder, bag mask device and basic airway device available. Dentists are additionally required to have adrenaline, salbutamol, aspirin and glyceryl trinitrate available. Dentists will be doing more invasive work than oral health therapists.

Spontaneous adverse event information for NZ is outlined below under adverse effects.

[REDACTED]

In a 2000/2001 study of the readiness of New Zealand dentists for medical emergencies Broadbent and Thomson reported that seven anaphylaxis events were reported by dentists over the previous 10-year period, with three attributed to lignocaine (patient reported lignocaine use before without any reaction), adrenaline in local anaesthetic, and an unspecified local anaesthetic.<sup>11</sup> All patients made rapid and full recoveries, following emergency management. Fourteen patients received overdoses of anaesthetic agents during the same period. Details were provided for six of these events, of which three were due to excessive local analgesics administered.

As an alternative to the mechanism of availability, standing orders could be used. This would not add any safety as they would allow product administration without a dentist on-site, and administration recorded in retrospect. Standing orders are cumbersome and time-consuming. The NZ workforce of dentists report stresses from time pressure,<sup>7</sup> thus standing orders would add burden and be less useful than a classification change.

### **Classification history**

Articaine was first considered for classification at the 32<sup>nd</sup> meeting of the Medicines Classification Committee in November 2004, when it became prescription-only. On 7 February 2014 articaine was gazetted as prescription “except when used as a local anaesthetic in practice by a dental therapist registered with the Dental Council”. This occurred following an out-of-session consultation of the Medicines Classification Committee in January 2014.

The 13<sup>th</sup> Medicines Classification Committee meeting in 1994 included a paper on local anaesthetics to tidy up inconsistencies in the classification of these medicines, given the confusion from a mix of scheduling of individual drugs and also a blanket entry for local anaesthetics. At this point, prilocaine became individually listed as a prescription medicine for parenteral use except when used by a dental therapist. It is presumed that lidocaine was already classified individually in this way as it was not individually mentioned in this section of the minutes.

Felypressin was a prescription medicine that was changed in classification to allow use by dental therapists after the 2004 32<sup>nd</sup> meeting of the Medicines Classification Committee. The minutes noted that “it was known to be widely used by dental therapists...” The committee agreed that it could be exempt from prescription when in combination with a local anaesthetic and used in practice by a dental therapist.

## 6. Interactions with other medicines

Interactions are likely to be very limited by the nature of the relatively local use and short half-life of the agents chosen.

Stockley's Drug Interactions<sup>9</sup> reports that there are no specific interactions for articaine (listed as carticaine in the database). Possible interactions with local anaesthetic use relevant to dental use are minimal. Nadolol 80 mg orally increases the mean duration of lidocaine 2% with 1:100,000 adrenaline by 17 minutes but not lidocaine alone. This is thought to result from increased local vasoconstriction. Prilocaine and lidocaine applied as Emla cream to a 12 week-old child also taking co-trimoxazole may have contributed to elevated methaemoglobin. It has therefore been suggested that this topical product not be used on infants under the age of 12 months who are receiving treatment with methaemoglobin-inducing drugs, including sulfonamides. There are no mentions in Stockleys of such an interaction with injectable local anaesthetics. The Citanest with Octapressin data sheet<sup>12</sup> suggests that "medicines which may predispose to methaemoglobin formation, e.g. sulphonamides, antimalarials and certain nitric compounds, could potentiate this adverse effect of prilocaine".

There is a caution in Stockley's about use of vasoconstrictors in local anaesthetics with tricyclic antidepressants, but they suggest that the interaction is only rarely clinically important, and aspiration would avoid inadvertent intravenous administration. Becker and Reed<sup>13</sup> also mention a potential interaction with vasoconstrictors with use of tricyclic antidepressants, monoamine oxidase inhibitors, digoxin, thyroxine or sympathomimetics for weight control or attention deficit disorders, and non-selective beta blockers. This is mentioned to be a caution rather than a contraindication. Felypressin is considered a safe alternative to adrenaline used in this way. Adrenaline at the concentrations used in dental local anaesthesia is classified as general sales.

Oral health therapists will not be using a large number of injections (more than 3-5 ml of 2% lignocaine with adrenaline) in a single sitting for a patient. Difficult work and extensive work is likely to be carried out either over multiple visits or is referred to a dentist instead. Furthermore, the SMARs data suggests minimal difficulties arising from drug interactions.

## 7. Contraindications and precautions

Hypersensitivity to any ingredient is a contraindication for use, in some cases this will include sodium metabisulphite.

Vasoconstrictors have a caution for use in hyperthyroidism and pregnancy.<sup>8</sup>

Dental care should be delayed in cases of very high blood pressure (e.g. 180/100).<sup>8</sup>

Hepatic cytochromes degrade amide type local anaesthetics, so severe hepatic disease requires caution with extensive use of these agents.<sup>14</sup> Reduced cardiac output slows delivery of amide type local anaesthetics to the liver, reducing their metabolism and prolonging the half-life.

For prilocaine, congenital or idiopathic methaemoglobinaemia is a contraindication.<sup>12</sup> This is noted to be rare.<sup>13</sup>

Concurrent sedation and opioids can increase risk.<sup>13</sup>

Datasheets note that caution is needed in patients with heart block; elderly; patients in poor general condition; severe or untreated hypertension; severe heart disease; severe anaemia or circulatory failure.<sup>12, 15</sup>

Intravascular injection must be avoided. Dental practitioners aspirate before administration to ensure a blood vessel has not been entered.

Contraindications and precautions are included in the education of oral health therapists. Oral health therapists will take a comprehensive medical history and consult with a dentist, or refer patients to a dentist if concerned that the patient could have contraindications and precautions for the use of local anaesthetic.

## **8. Possible resistance**

Not applicable.

## **9. Adverse events – nature, frequency, etc.**

Systemic adverse events depend on plasma levels. A local anaesthetic provides a concentrated effect locally. A vasoconstrictor is commonly used to minimise systemic toxicity.<sup>5, 14</sup> Repeated injections, particularly in children, or inadvertent injection into a blood vessel can cause overdose. Overdose with the local anaesthetic agent can cause headaches, light-headedness, dizziness, blurred vision, tinnitus, numb mouth, drowsiness, disorientation and loss of consciousness.<sup>8</sup> CNS stimulation (including seizures) is followed by CNS depression.<sup>14</sup> Adverse effects on the cardiovascular system are uncommon.<sup>14</sup> Adverse drug events with amide-type local anaesthetics (including prilocaine, lidocaine and articaine) for dental use are very rare.<sup>1, 12</sup>

Becker and Reed report that lidocaine toxicity is seen at plasma concentrations of 5 micrograms/mL, with convulsive seizures occurring above 10 micrograms/mL.<sup>13</sup> A 2% lidocaine injection in 2mL in a cartridge will contain 40 mg of lidocaine. Becker and Reed suggested that lidocaine systemic absorption from dental injections would be likely to be similar to that of a study using vaginal application in which 400 mg (equivalent to 10 cartridges, far greater quantity than would be used in practice) provided close to 5 micrograms/mL plasma concentrations, and about half of that dose if used with adrenaline. A further study mentioned by Becker and Reed found 480 mg of articaine with adrenaline saw a 2 microgram/mL plasma concentration. These authors stated that “one can reasonably conclude that adhering to published maximum recommended dosages for local anesthetics will not result in systemic serum levels that approach those associated with toxicity.”

Paraesthesias can occur rarely with local anaesthetics, with 95% occurring with mandibular nerve blocks.<sup>13</sup>

Vasoconstrictors can delay wound healing, cause tissue oedema, and tissue necrosis, and therefore are not recommended for use with local anaesthetics in areas with limited collateral circulation.<sup>14</sup>

Dental use occurs in areas of sufficient circulation. In overdose, felypressin can increase blood pressure or cause coronary constriction.<sup>12</sup> Dental use of adrenaline in doses of 1:100,000 increases cardiac output, heart rate and stroke volume.<sup>13</sup> However, adrenaline is quickly metabolised, so the effects are short-lived.

An expert in local anaesthetic use in dentistry, Professor Stanley Malamed, described allergy with amide-type local anaesthetics as being “such a rarity as to be virtually non-existent”.<sup>1</sup> Goodman and Gillman’s *Pharmacological Basis of Therapeutics*<sup>14</sup> is more circumspect, noting that hypersensitivity is rare for the amide-type local anaesthetics, and less common than with the ester type local anaesthetics (e.g. procaine). Preservatives such as parabens or added sulphite for local anaesthetics combined with a vasoconstrictor, could cause allergy. Dental injections are typically contained in cartridges for single use, so do not contain parabens. As it is estimated that in the US over 300 million cartridges of LA are administered each year by dental practitioners,<sup>1</sup> it could reasonably be expected that serious allergic reactions would be well understood. Malamed noted in 2003, for example, that articaine has been marketed since 1975 and was reported to be in around 131 countries, yet that there had been no reported cases of allergy to it.<sup>1</sup> Allergy can include dermatitis, or an asthma attack. Greenwood and Meechan in 2014 reported that anaphylaxis in dental practice was more likely to occur with latex or penicillin than with local anaesthetic use.<sup>16</sup> NZ spontaneous reporting adverse event data (outlined below) shows some cases of anaphylaxis reported with dental anaesthetic injections containing lidocaine, prilocaine or articaine with or without a vasoconstrictor.

Methaemaglobinaemia can occur with prilocaine at high doses (usually greater than 8 mg/kg), but not lidocaine nor articaine.<sup>14</sup> This effect has limited the use of prilocaine to dentistry. Becker and Reed<sup>13</sup> note that this effect is “unlikely to follow the administration of recommended doses”.

Spontaneous reporting data from NZ (SMARs) for the medicines being discussed shows no reports for articaine alone, and 12 reports for articaine with adrenaline, with no deaths. One SMARs reports is for bronchospasm in a 14 year old; another for hypotension, rash and stridor in a 56 year old; one for anaphylactic shock and cardiac arrest (with a positive skin test) in a 44 year old; and one for depressed level of consciousness in a 49 year old. Articaine seems to be used primarily for dental use, with anecdotal reports of high usage by dental practitioners. Broadbent and Thomson reported that for the period 1990-2000, New Zealand dentists reported a total of 166 allergic reactions, of which details for 57 events were provided—16 events caused by local anaesthetics agents were reported.<sup>11</sup>

For lidocaine injection, SMARs data reports of 109 cases from 2000 to 2016 included anaphylactic reactions in 15 people aged 16 to 79 years, sometimes with concomitant suspected medicines. It was not clear how many of these were dental use. There were no deaths. Anaphylaxis also occurred with topical lidocaine. Other reports with lidocaine injection included anaphylactoid reactions, angioedema and rashes.

For prilocaine injection, SMARs data reports of 17 cases from 2000 to 2016 did not include any deaths. Two anaphylactic reactions were reported, including one reaction in a 15 year old. One case of methaemaglobinaemia was reported in a 21 year old. An 87 year old using prilocaine with felypressin had a cerebral haemorrhage, dyspnoea, hypertension, seizure and vomiting. Bronchospasm and rashes were also reported.

For felypressin there were four reports, in all cases felypressin was combined with prilocaine so these reports are included in the prilocaine reports, above.

Some of the products contain sulphites as an antioxidant where adrenaline is included, e.g. Ubistesin® (articaine with adrenaline),<sup>17</sup> and Xylocaine dental with adrenaline 1:80,000.<sup>15</sup> This excipient can cause allergy in its own right. Asthmatics and atopic patients are more likely to be allergic to sulphites.<sup>13</sup>

Dental practitioners are taught to inject the local anaesthetic slowly after negative aspiration to minimise adverse events.

#### **10. Potential for abuse or misuse**

Nil.

#### **11. Other information**

##### **Articaine**

Articaine may be less familiar to non-dental health practitioners. It is also known as carticaine, and is an amide-type local anaesthetic. It has a rapid onset (1-6 minutes) and short duration of action (about one hour),<sup>14</sup> making it very commonly used in dentistry in New Zealand and internationally.

##### **Stakeholder engagement**

We have engaged with a wide range of stakeholders. There is a strong flavour from this support that the education is appropriate and use of local anaesthetics by oral health therapists is appropriate without needing a dentist on-site. See the appendix 2 for further information.

## **SUMMARY**

Local anaesthetic agents are widely used in NZ and internationally by dentists and other dental professionals. NZ has a long history of these agents being used by dental therapists for children up to 18 years of age, and by dental hygienists on all patients-with a dentist on-site. NZ spontaneous reports of adverse events have shown few concerns apart from occasional anaphylaxis. The Dental Council has consulted widely on the scope of practice for oral health therapists, which includes local anaesthetic administration without requiring a dentist to be on-site. Most submitters were supportive of the scope of practice consulted on. We have further engaged with stakeholders for this application, and received considerable support of the classification statements we have proposed.

Oral health therapists have had appropriate education in use of these agents in their university degree course. They are trained, as are dentists, to CORE Immediate resuscitation level. Oral health therapists, dental therapists and dental hygienists are increasingly working more independently, including Australia, UK, Singapore after 5 years, and some states in the USA.

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