

MANITOBA DENTAL ASSOCIATION



BYLAW FOR THE USE OF NEUROMODULATORS AND DERMAL FILLERS

MANITOBA DENTAL ASSOCIATION
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Board Approval for Bylaw Distribution:
Member Ratification of Bylaw:

PREAMBLE

Botulinum toxin blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals and inhibiting the release of acetylcholine. Injectable drugs (neuromodulators) derived from this paralytic agent are listed in Schedule 1 of the Manual for Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities.

Neuromodulators in therapeutic doses produces partial chemical denervation of the muscle resulting in reduction in localized muscle activity and potential muscle atrophy. Reinnervation of the muscle may occur over time reversing the effect of the toxin.

Neuromodulators are available under a variety of proprietary and non-proprietary names with each product having its own individual potency which cannot be used interchangeably. The labeled usage of each product may vary.

A dentist may use any legally prescribed drugs to diagnose, manage or treat a patient if the use is within the scope of practice of dentistry.

Dermal fillers are temporary (absorbable) or permanent (non-absorbable) medical devices injected into the soft tissue to diminish facial lines and restore volume in the face.

Dermal fillers are available under a variety of proprietary and non-proprietary names for temporary (absorbable) or permanent (non-absorbable) purposes.

A dentist may use any medical device licensed for sale by Health Canada to manage or treat a patient if the use is within the scope of practice of dentistry.

The purpose of this bylaw is to:

1. protect the public by authorizing access to services in a regulated manner;
2. define the usage of neuromodulators and dermal fillers for members in the Province;
3. establish rosters identifying members authorized use of neuromodulators and dermal fillers;
4. mandate specific requirements for members using neuromodulators and dermal fillers.

Members may make a written request to the Registrar for modification of the document or continuing competence requirements based on their individual practice circumstances. Upon review, the Registrar may allow modifications to the document or continuing competence requirements if they do not reduce the intent or purpose of those requirements. A member must continue to comply with the document or continuing competence requirements of this bylaw until a modification is approved by the Registrar.

SECTION I – NEUROMODULATORS FOR MYOFASCIAL PAIN AND PARAFUNCTION

Uses of neuromodulators may include treatment for the management of bruxism (diurnal or nocturnal parafunctional activity that includes tooth clenching or grinding.)

Uses of neuromodulators may include treatment for the management of headaches, migraines, and temporomandibular disorders within the scope of the practise of dentistry.

1. INITIAL QUALIFICATIONS/TRAINING

NEW REGISTRANTS

- a. For ambulatory patients over the age of 16, a member may apply for registration to perform dental services using neuromodulators limited for the management of bruxism [extraoral mastication muscles (temporalis and masseter)]. The applicant must submit evidence satisfactory to the Registrar that meets all of the following:
 - i. completed an MDA approved course of study, with formal evaluation on anatomy, pharmacology and physiology relevant to neuromodulator use with a minimum of 8 hours didactic instruction and 4 hours hands-on anatomical cadaver laboratory;
 - ii. completed an MDA approved course of study, with formal evaluation on the diagnosis, etiology, techniques, administration, and risk management relevant to neuromodulator use for the management of bruxism with a minimum of 8 hours didactic instruction; and
 - iii. completed an MDA approved course of study with a minimum of 8 hours of clinical hands-on training, involving the use of neuromodulators.
- b. For ambulatory patients over the age of 16, a member may apply for registration to perform dental services using neuromodulators for the management of myofascial pain and parafunction (not limited to bruxism). The applicant must submit evidence satisfactory to the Registrar that meets all of the following:
 - i. completed an MDA approved course of study, with formal evaluation on anatomy, pharmacology and physiology relevant to neuromodulator use with a minimum of 8 hours didactic instruction and 4 hours hands-on anatomical cadaver laboratory;
 - ii. completed an MDA approved course of study, with formal evaluation on the diagnosis, etiology, techniques, administration, and risk management specific to neuromodulator use for the management of myofascial pain and parafunction with a minimum of 8 hours didactic instruction; and
 - iii. completed an MDA approved course of study with a minimum of 8 hours of clinical training, involving the use of neuromodulators for the management of myofascial pain and parafunction, including supervised direct treatment by the member on a minimum of 5 patients.

2. CONTINUING COMPETENCE

ALL MEMBERS

- a. Must maintain a separate contemporaneous log of all patient management involving neuromodulators. Log must be available at request of Registrar and must include the following:
 - i. patient name;
 - ii. purpose; and
 - iii. neuromodulator type and dosage used
 - b. Must complete a dental regulatory authority (DRA) recognized course of study with a minimum of 9 hours of didactic instruction specific to the use of neuromodulators in the members continuing education cycle as defined in the MDA *Bylaw for Continuing Education of Dentists*.
 - c. Evidence satisfactory to the Registrar of continuing competency must be available on MDA request.
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SECTION II – NEUROMODULATORS FOR OTHER USES

The use of neuromodulators will be considered for upper facial purposes only if the member limits the use of the neuromodulator to the frontalis muscle, the glabellar complex, procerus, the corrugators supercilii, and orbicularis oculi.

The use of neuromodulators will be considered for mid-facial, lower facial and the neck purposes only if a member limits the use of the neuromodulator to superficial muscles in these areas (levator labii superioris alaeque nasi, levator labii superioris, nasalis, zygomaticus major and minor, risorius, levator and depressor anguli oris, buccinator, orbicularis oris, levator and depressor labii superioris, mentalis and platysma).

1. INITIAL QUALIFICATIONS/TRAINING

NEW REGISTRANTS

- a. For ambulatory patients over the age of 16, a member may apply for registration to perform dental services using neuromodulators for treatment involving the upper face. The applicant must submit evidence satisfactory to the Registrar that meets all of the following:
 - i. completed an MDA approved course of study, with formal evaluation on anatomy, pharmacology and physiology relevant to neuromodulator use with a minimum of 8 hours didactic instruction and 4 hours hands-on anatomical cadaver laboratory;

- ii. completed an MDA approved course of study, with formal evaluation on the diagnosis, etiology, techniques, administration, and risk management relevant to neuromodulator use for the superficial upper facial muscles with a minimum of 8 hours didactic instruction; and
 - iii. completed an MDA approved course of study with a minimum of 8 hours of clinical hands-on training involving the use of neuromodulators.
- b. For ambulatory patients over the age of 16, a member may apply for registration to perform dental services using neuromodulators for treatment involving the mid-face, lower face, and the neck. The applicant must submit evidence satisfactory to the Registrar that meets all of the following:
 - i. completed an MDA approved course of study, with formal evaluation on anatomy, pharmacology and physiology relevant to neuromodulator use with a minimum of 8 hours didactic instruction and 4 hours hands-on anatomical cadaver laboratory;
 - ii. completed an MDA approved course of study, with formal evaluation on the diagnosis, etiology, techniques, administration, and risk management relevant to neuromodulator use for the mid-face, lower face, and neck with a minimum of 8 hours didactic instruction; and
 - iii. completed an MDA approved course of study with a minimum of 8 hours of clinical training, involving the use of neuromodulators for treatment of the mid-face, lower face and neck, including supervised direct treatment by the member on a minimum of 5 patients.

2. CONTINUING COMPETENCE

ALL MEMBERS

- a. Must maintain a separate contemporaneous log of all patient treatment involving neuromodulators. Log must be available at request of Registrar and must include the following:
 - i. patient name;
 - ii. purpose; and
 - iii. neuromodulator type and dosage used
- b. Must complete a DRA recognized course of study with a minimum of 9 hours of didactic instruction specific to the use of neuromodulators in the members continuing education cycle as defined in the MDA Bylaw for Continuing Education of Dentists.
- c. Evidence satisfactory to the Registrar of continuing competency must be available on MDA request.

SECTION III – DERMAL FILLERS

The use of dermal fillers for the treatment of the naso-labial fold, lip augmentation, gingival augmentation and other areas of the face, including but not limited to: malar enhancement, treatment of the nasojugal groove, and the treatment of glabellar, laugh and marionette lines.

1. INITIAL QUALIFICATIONS/TRAINING

NEW REGISTRANTS

- a. For ambulatory adult patients, a member may apply for registration to perform dental services for the use of facial dermal fillers.
- b. The applicant must submit evidence satisfactory to the Registrar that meets all of the following:
 - i. completed an MDA approved course of study, with formal evaluation on anatomy, pharmacology and physiology relevant to dermal filler use with a minimum of 8 hours didactic instruction and 4 hours hands- on anatomical cadaver laboratory;
 - ii. completed a course of study, recognized by the MDA, with a minimum of 8 hours of didactic instruction specific to the use and treatment of facial dermal fillers in the last five years; and
 - iii. completed an MDA approved course of study with a minimum of 8 hours of clinical training, involving the use of dermal fillers, including supervised direct treatment by the member on a minimum of 5 patients.

2. CONTINUING COMPETENCE

ALL MEMBERS

- a. Must maintain a separate contemporaneous log of all patient treatment involving neuromodulators. Log must be available at request of Registrar and must include the following:
 - i. patient name;
 - ii. purpose; and
 - iii. dermal filler type, concentration and specific anatomical locations administered.
- b. Must complete a DRA recognized course of study with a minimum of 9 hours of didactic instruction specific to the use of dermal fillers in the members continuing education cycle as defined in the MDA Bylaw for Continuing Education of Dentists.
- c. Evidence satisfactory to the Registrar of continuing competency must be available on MDA request.

SECTION IV – RECORDKEEPING

1. A member shall record in the patient chart all treatment contemporaneous with neuromodulator and/or dermal filler use, including but not limited to:
 - a. medical history and clinical examination;
 - b. review of patient motivation and expectations;
 - c. informed consent identifying risks and benefits specific to patient circumstances;
 - d. comprehensive treatment plan;
 - e. neuromodulator type, dosage and specific anatomical locations administered (as applicable);
 - f. dermal filler type, concentration and specific anatomical locations administered (as applicable);
 - g. pre-operative diagnostic and post-operative photographs; and
 - h. any adverse reactions or incidences during or after neuromodulator and/or dermal filler administration.

SECTION V – MEMBER MARKETING OF NEUROMODULATORS AND DERMAL FILLERS

1. A member shall not advertise, market, or make any representation by any means whatever for the purpose of promoting directly or indirectly the sale, provision of treatment or services related to neuromodulators and/or dermal fillers except in compliance with federal Food and Drug Act, Food and Drug Regulations, Health Canada Policies, MDA *Code of Ethics* and any MDA Board approved standard of practice.

SECTION VI – REGISTRY OF MEMBERS AUTHORIZED FOR THE USE OF NEUROMODULATORS AND DERMAL FILLERS

1. The Registrar shall include a member on the public registry if he or she is registered to provide dental services for the use of neuromodulators and dermal fillers utilizing one or more of the following treatment areas in a format approved by the Registrar:

- a. neuromodulators for myofascial pain and parafunction ;
 - i. neuromodulator use limited to the management of bruxism;
 - ii. neuromodulator use for the management of myofascial pain and parafunction.
 - b. neuromodulators for other uses:
 - i. upper face;
 - ii. mid-face, lower face, and neck.
 - c. facial dermal fillers
2. A member shall be registered to provide dental services using one or more of the dental services listed in subsection VI(1) if:
- a. is on the current public registry; or
 - b. completed and signed application in the form approved by the Board;
 - c. evidence satisfactory to the Registrar of identity and current legal name;
 - d. evidence satisfactory to the Registrar the member meets the registration requirements set out in this bylaw;
 - e. payment of applicable registration and permit fees (SCHEDULE A - FEES);
 - f. payment of any other outstanding fine, fee, debt or levy owed by the applicant to the MDA; and
 - g. any other information that in the opinion of the Registrar is required to review the registration application of a member.
3. A member shall have his or her name removed from this registry if in the opinion of the Registrar;
- a. the member submits a written notice of cancellation of the permit in a form approved by the Board;
 - b. there is evidence the member is utilizing neuromodulator and/or dermal filler modalities beyond the conditions provided in this bylaw;
 - c. the member fails to meet the continuing competency requirements set out in this bylaw;
or
 - d. any other situation where there is evidence the member presents a potential risk to patients or the public in the utilization of these modalities.
4. Nothing in this section shall be interpreted as in any way affecting the ability of the Registrar to include additional restrictions, conditions or limitations on a member registered to provide dental services using one or more of the dental services listed in subsection VI(1).
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SECTION XI – APPEAL OF A REGISTRATION DECISION BY THE REGISTRAR

1. A member may appeal a registration decision by the Registrar to the MDA Board.
 - a. An applicant has thirty days from written notification of the decision to send an appeal submission to the MDA Board along with a non-refundable appeal fee (SCHEDULE A).
 - b. The Board shall select from amongst its voting directors three directors to compose an appeal committee by its own process. The appeal committee must include at least one public representative.
 - c. The appeal committee shall schedule the appeal review within sixty days of receiving the appeal.
 - d. The appeal committee shall provide the applicant written notice of the date, time and place of the review.
 - e. In reviewing the decision appeal, the appeal committee shall consider only the following:
 - i. original application and supporting documentation;
 - ii. Registrar's written decision and reasons for decision;
 - iii. applicant written appeal submission and supporting documents; and
 - iv. Registrar's written response to appeal submission.
 - f. The appeal committee may make the following determinations:
 - i. confirm the Registrar's decision;
 - ii. vary the Registrar's decision with a decision the appeal committee determines appropriate; or
 - iii. refer the matter back to the Registrar for further consideration with direction.
 - g. The appeal committee shall provide the Registrar and the member a written decision and reason for decision within thirty days of making the decision.
 2. The Registrar shall implement any decision of the appeal committee within a time period dependent on the nature of the decision.
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SECTION XII – NOTIFICATION OF CHANGE

1. A member shall notify the Registrar in a form approved by the Board of any change in name, contact information or location providing treatment using neuromodulators and/or dermal fillers within fifteen days of the change.

Bylaw for the Use of Botulinum Toxin of the Manitoba Dental Association is hereby repealed.

DONE and PASSED by the Board of Directors of the Manitoba Dental Association at
Winnipeg, Manitoba this _____ day of _____.

President Secretary

This bylaw will become effective on the _____, unless 10 members request on or before
the _____ in writing, its ratification at a general meeting of the Association pursuant to ss.
43(2) of The Dental Association Act.