

Symptom Management Algorithm

Medication Related Osteonecrosis of the Jaw (MRONJ) in Adults with Cancer

About Medication-Related Osteonecrosis of the Jaw (MRONJ)

What is MRONJ?

- MRONJ is defined by three criteria:
 - o Exposed bone, or bone that can be probed through an intraoral or extraoral fistula in the maxillofacial region
 - o Condition has persisted for more than 8 weeks in patients with current or previous exposure to antiresorptive or antiangiogenic agents
 - Patient has no history of radiation therapy of the jaws
- Symptoms of MRONJ can include pain and purulent discharge, or it may be asymptomatic
- Current opinion is that MRONJ is a multifactorial complication that can develop through various pathogenic mechanisms

What Are the Risk Factors?

- The risk of developing MRONJ depends on several factors, including:
 - Therapeutic indications
 - Types of medication
 - Duration of exposure to the drugs
- Other risk factors to consider:
 - o Current oral issues, e.g. ill-fitting dentures, extensive decay, periodontal disease
 - o Systemic disease, e.g. cancer, diabetes, renal dialysis
 - o Lifestyle factors, e.g. smoking, drinking, obesity
 - o Co-administered agents, e.g. anticancer agents, corticosteroids

How Do Bone Modifying Agents (BMA) and Antiangiogenic Agents Increase Risk of MRONJ?

- MRONJ is associated with use of antiresorptive drugs such as bisphosphonates or denosumab. See table 1 for BMA dosing information (page 5)
- The mechanism by which BMAs cause MRONJ are still unclear. Hypotheses to explain the localization of this condition to the jaws include:
- Inhibition of bone remodeling and excessive suppression of osteoclast activity by antiresorptive drugs. There may also be an association with antiangiogenic agents, which requires further study
 - o Altered production of proinflammatory cytokines and impairment of the immune response to infection by these medications
 - Inhibition of angiogenesis
 - o Tissue toxicity caused by the antiresorptive agents

MRONJ Examples



Figure 1: MRONJ right lingual mandible (most common site for MRONJ); AAOMS^{*} Stage 1



Figure 2: Process of boney sequestration in MRONJ patient



Figure 3: MRONJ right maxilla; AAOMS^{*} Stage 1

Prevention

Prevention Consideration for All Patients

- Good oral care is important to prevent and decrease oral complications, to maintain normal function of the oral tissues, to maintain comfort, and to reduce the risk of local and systemic infection. See the Basic Oral Care Tables (pages 7 and 8)
- A referral for oral care assessment (including a comprehensive dental, periodontal, and oral radiographic exam, when feasible) should be undertaken before initiating therapy for patients receiving a BMA in a non-urgent setting
- Modifiable risk factors (poor oral health, invasive dental procedures, ill-fitting dentures, uncontrolled diabetes mellitus, tobacco use, alcohol use, etc.) should be addressed with the patient as early as possible
- Do not perform elective dentoalveolar surgical procedures (e.g. non-medically necessary extractions, alveoloplasties, implants, etc.) during active
 therapy with a BMA at an oncologic dose. Exceptions may be considered when a dental specialist with expertise in prevention and treatment of MRONJ
 has reviewed the benefits and risks of the proposed invasive procedure with the patient and the oncology team
- If dentoalveolar surgery is performed, patients should be evaluated by the dental specialist on a systematic and frequently scheduled basis (e.g. every 6 to 8 weeks) until full mucosal coverage of the surgical site has occurred
- Administration of the BMA may be deferred before dentoalveolar surgery at the discretion of the treating physician in conjunction with patient and oral health provider input

Assessment

Adapted MRONJ As	sessment Acronym: OPQRSTUV (Adapted from Fraser Health ¹)
Onset	When did the symptoms begin? How often do they occur? How long do they last?
Provoking/Palliating	What brings it on? What makes it better? What makes it worse?
Quality	• Do you have a dull ache, oral bleeding, numbness of the lip, or feeling of a toothache? Is there something that feels sharp in your mouth?
Region/Radiation	• Where are your symptoms (e.g. on lips, tongue, mouth)? Does your pain radiate anywhere? Do you have any other related or associated symptoms?
Severity	• What is the intensity of this symptom (on a scale of 0 to 10, with 0 being none and 10 being worst possible)? Right now? At best? At worst? On average?
Treatment	 Medications: Are you currently using, or previously treated with, a bone modifying agent (BMA) or an angiogenic inhibitor? Have you had radiation therapy to your jaw? Have you had metastatic disease to your jaw?
Understanding/ Impact on you	 How bothered are you by this symptom? Is your ability to eat or drink affected? By how much? Are you having difficulty swallowing or chewing? Is it for solids, liquids, or both? Do you have any weight loss? How much? Over what time frame? Are you able to wear dentures? Do any of your symptoms interfere with other normal activities? How does this symptom affect your day to day life?
Values	Are there any other worries or concerns about this symptom that you or your family have?

Clinical Assessment Considerations for All Patients

- Significant risk factors for the development of oral complications include the type of cancer, type of cancer treatments, cumulative doses of chemotherapy or radiation treatment (current or prior), method of delivery, and duration of treatment
- Predisposing medical, dental, and lifestyle factors such as uncontrolled diabetes, pre-existing autoimmune conditions, polypharmacy, tobacco and alcohol use, and non-compliance with oral care may increase severity of oral complications
- Oral complications can significantly affect the patient's morbidity, ability to tolerate treatment, and overall quality of life
- Rigorous assessment, diagnosis, and early intervention are important in preventing and decreasing oral complications. This includes the assessment of
 nutritional status and adequacy of oral intake
- A large variety of medications may cause oral complications. Consultation with the prescriber, dental provider, and/or pharmacist is strongly recommended
- Some pharmaceuticals may be unaffordable, and alternatives should be offered where possible
- If odontogenic or periodontal infection is suspected, consultation with a oncology team is strongly recommended

Management

Management Considerations for All Patients

- The initial approach to treatment should be conservative. Conservative measures may include antimicrobial mouth rinses, antibiotics (if clinically indicated), effective oral hygiene, and conservative surgical interventions (e.g. removal of a superficial bone spicule)
- If MRONJ results in persistent symptoms or affects function despite initial conservative treatment, aggressive surgical interventions may be used (e.g. mucosal flap elevation, block resection of necrotic bone, soft tissue closure)
- Aggressive surgical intervention is not recommended for asymptomatic bone exposure
- See table 2 for descriptions of complete, partial, and minimal dental clearance protocols by dental pathology (page 5)
- For patients diagnosed with MRONJ while being treated with BMAs, administration of the BMA may be deferred at the discretion of the treating physician, in conjunction with patient and oral health provider input
- See table 4 for the management flow diagram for BMAs (page 6)

Treatment

Treatment by Stage (Adapted from the MRONJ: MASCC/ISOO/ASCO Clinical Practice Guideline ²)		
Stage	Treatment Strategy*	
At Risk: No apparent necrotic bone in patients who have been treated with oral or intravenous bone-modifying agents (BMA)	 No treatment indicated Patient education and reduction of modifiable risk factors 	
Increased Risk: No clinical evidence of necrotic bone but nonspecific clinical findings, radiographic changes, and symptoms	 Symptomatic management, including the use of pain medication, close scrutiny, and follow up Refer to dental specialist and follow up every 8 weeks with communication of lesion status to the oncologist Patient education and reduction of modifiable risk factors 	
Stage 1: Exposed and necrotic bone or fistulas that probe to bone in patients who are asymptomatic and have no evidence of infection	 Antibacterial mouth rinse Clinical follow up every 8 weeks by dental specialist with communication of lesion status to oncologist Patient education and reduction of modifiable risk factors 	
Stage 2: Exposed and necrotic bone or fistulas that probe to bone, associated with infection as evidenced by pain and erythema (redness) in the region of exposed bone, with or without purulent drainage	 Symptomatic treatment with oral antibiotics and topical antibacterial rinse Pain control Debridement to relieve soft tissue irritation and infection control Clinical follow-up every 8 weeks by dental specialist with communication of lesion status to oncologist Patient education and reduction of modifiable risk factors 	
 Stage 3: Exposed and necrotic bone or a fistula that probes to bone in patients with pain, infection, and one or more of the following: Exposed and necrotic bone extending beyond the region of alveolar bone (i.e. inferior border and ramus in mandible maxillary sinus, and zygoma in maxilla) resulting in pathologic fracture Extra-oral fistula, oral antral, or oral nasal communication Osteolysis extending to the inferior border of the mandible or sinus floor 	 Symptomatic treatment with oral antibiotics and topical antibacterial rinse Pain control Surgical debridement or resection for long-term palliation of infection and pain Clinical follow-up every 8 weeks by dental specialist with communication of lesion status to oncologist Patient education and reduction of modifiable risk factors 	

Follow-up and Ongoing Monitoring

- During the course of MRONJ treatment, the dentist or dental specialist should communicate the objective and subjective status of the lesion (i.e. resolved, improving, stable, or progressive) with the medical oncologist
- See table 3 for how to characterize MRONJ after treatment (page 5)

• The clinical course of MRONJ may impact local and/or systemic treatment decisions with respect to cessation or recommencement of BMAs

Reference Tables

Table 1: Dosing Table - Bone-Modifying Agents [*]				
Medication	Indication	Dose & Route	Schedule	Frequency of MRONJ
Pamidronate	Bone metastases of solid tumorsMultiple myeloma	90mg intravenous	Every 3 to 4 weeks	3.2—5.0
Zoledronic acid	Bone metastases of solid tumorsMultiple myeloma	4mg intravenous	Every 3 to 4 weeks, or 12 weeks	1.0—8.0
Zoledronic acid	Adjuvant treatment	4mg intravenous	Every 3 to 6 months	0.0—1.8
Denosumab	Bone metastases of solid tumors	120mg subcutaneous	Every 4 weeks	0.7—6.9
Denosumab	Adjuvant treatment	60mg subcutaneous	Every 6 months	0.0

Table 2: Descriptions of Complete, Partial and Minimal Dental Clearance Protocols by Dental Pathology, for Dental Providers*

Dental Pathology	Complete	Partial	Minimal/Incomplete/ No Clearance
Caries	Restore all teeth	Restore mild/moderate caries if time permits, otherwise leave lesions alone and observe	
Severe Caries/Pulp Involvement/ Dental Abscess	Root canal	treatment or extract	
Apical Periodontitis	 Retreat Apicoectomy Extract	 Treat symptomatic lesions and lesions ≥ 5mm Observe asymptomatic lesions and lesions <5mm 	Intervention only if
Advanced Periodontal Disease (PDD)	Extract teeth with: ● Probing depth ≥ 6mm ● Furcation I, II, III	 Extract teeth with: Probing depth ≥ 8mm Mobility III Severe inflammation 	symptomatic
Partially Erupted Third Molars	Extract	 Observe asymptomatic teeth Extract partially erupted third molars with purulence of pericoronitis 	

Table 3: Characterizing MRONJ After Treatment				
Term	Mucosal Coverage	Symptom/Pain	Sign of Infection/Inflammation	Radiographic
Resolved	Complete healing	No pain	None	Trabecular pattern, formation lamina dura resorbed
Improving	Significant improvement (>50% of mucosal coverage)	Significant improvement (>50% reduction of pain, visual analog scale (VAS))	Significant improvement (no signs of infection/inflammation)	Improved trabecular pattern, signs of sequestra
Stable	Mild improvement (<50% of mucosal coverage)	Mild improvement (<50% reduction of pain, VAS)	Mild improvement (mild signs of infection/inflammation)	No changes
Progressive	No improvement or worsening	No improvement or worsening	No improvement	Lytic changes, decreasing trabeculation, increased size of radiographic lesion

Table 4 – MRONJ I (Adapted from MRO	Management Flow Diagram, Bone-Modifying Agent (BMA) DNJ: MASCC/ISOO/ASCO Clinical Practice Guideline ²)	
Oncologist Dentist	 Consider continuation versus discontinuation of BMA therapy in patients newly diagnosed with MRONJ Inform patient of required dental assessments and need for commitment to oral care Refer patient to own family dentist or a dentist that is identified as liaison to cancer program Reinforce modifiable risk factors: invasive dental procedure, diabetes, periodontal disease, denture use, and smoking Provide the dentist with the patient's medical diagnosis and antiresorptive Indicate if patient has already commenced therapy and duration 	Dentist Dentist G-month management follow-up and angiogenic inhibitor profile
Dentist Oncologist	 Send dental diagnosis and treatment plan to oncologist Coordinate with oncologist if oral surgery is necessary Identify any modifiable risk factors: invasive dental procedure, diabetes, p 	eriodontal disease, denture use, and smoking
Dentist	 Patients referred from the oncologist should be seen by the dentist within schedule with the dentist Evaluate modifiable risk factors: invasive dental procedure, diabetes, period Before antiresorptive therapy: Conduct complete dental examination with orthopantomography and Perform necessary dental extractions Conduct conservative dental and periodontal interventions Adjust prosthetics, if necessary Educate the patient about the need for lifelong daily commitment to co Encourage the correction of risk factors (e.g. smoking, uncontrolled di During antiresorptive therapy: Conduct complete dental examination with orthopantomography and Encourage follow-up visits every 4 to 6 months Evaluate oral mucosa integrity Orthopantomography annually Reinforce ongoing education on the importance of maintaining good co Continue to reinforce modifiable risk factors (e.g. smoking, uncontrolled 	2 weeks of referral date and be on a 6 month follow-up odontal disease, denture use, and smoking intraoral radiographs oral care. See the basic oral care tables (pages 7 and 8) abetes) intraoral radiographs oral hygiene. See the basic oral care tables (pages 7 and 8) ed diabetes)
Oncologist Dentist Dental Specialist	 When a suspected MRONJ is observed by a dentist or an oncology, the despecialist for additional treatment management Potential differential diagnoses include: Necrotic dental pulp with apical abscess Periodontal abscess Reversible or irreversible pulpitis (could be secondary to bruxism) Maxillary sinus pain (acute or chronic sinusitis) Myofascial pain Dental caries 	ntist or oncologist should refer the patient to a dental
Dental Specialist	 Management is determined by stage, severity of symptoms, functional in follow-up schedule. See the treatment section for more details (page 4) At risk: no apparent necrotic bone in patients who have been treated with Stage 1: conservative therapy, improve oral hygiene. Treat active dental a Stage 2: as in stage 1, also treat symptoms, systemic antibiotics if infectio Stage 3: as in stage 2, also surgical debridement, and resection including j 	npact and overall prognosis and should be on an 8 week n oral or intravenous BMAs and periodontal disease, topical antibiotic mouth rinses n is suspected, and consider surgical debridement aw reconstruction, if necessary
Oncologist Dental Specialist	 Based on the stage of MRONJ, the dental specialist designs a treatment p treatment plan to the oncologist. Patient should be on an 8 week follow-to Follows patient's lesion status and report to the oncologist Lesion status. See table 3 for how to characterize MRONJ after treatment o Resolved: Complete healing Lesting Complete healing 	lan for the management of MRONJ and reports the up schedule with the oral specialist (page 5):

- Improving: Significant improvement (> 50% of mucosal coverage)
- Stable: Mild improvement (< 50% of mucosal coverage)
- o Progressive: No improvement
- Continue to reinforce modifiable risk factors: invasive dental procedure, diabetes, periodontal disease, denture use, and smoking

Basic Oral Care Tables

Flossing

Basic	 Patients who have not flossed routinely before cancer treatment should not begin flossing at this time Patients with mouth cancers, trismus, dysphagia, and/or dysgeusia may not be able to floss; use of interproximal brushes can replace flossing Floss at least once daily Waxed floss may be easier to use and minimize trauma to the gums
Intensified	Continue with basic plan until discomfort becomes too great
End of Life	Discontinue flossing if patient chooses

Brushing

Basic	 Use a small, ultra-soft-headed, rounded-end, bristle toothbrush (an ultrasonic toothbrush, may be acceptable) Rinse toothbrush in hot water to soften the brush before using Use a prescription strength fluoride toothpaste. Spit out the foam but do not rinse mouth Use a fluoridated toothpaste and re-mineralizing toothpaste containing calcium and phosphate Brush tongue gently from back to front, using a sweeping motion Rinse brush after use in hot water and allow to air dry Change toothbrush when bristles are not standing up straight Brush within 30 minutes after eating and before bed. Ensure the gingival portion of the tooth and periodontal sulcus (where the tooth and gums meet) are included Consider topical anesthetics (e.g. viscous lidocaine 2% or viscous xylocaine 2%, 2-5 mL) before brushing and eating to minimize pain With continuous pain, a regularly prescribed oral analgesic allows for more thorough tooth brushing 	Resta F a Bland 1 S Lidoo C 6 n Patie • B
Intensified	 Encourage patient to continue brushing through treatment phase even when it causes discomfort If bleeding occurs, encourage gentler brushing Use a non-flavoured, non-alcoholic chlorhexidine gluconate (CHX) 0.12% rinse to aid in plaque control, 2 times a day after meals If unable to continue brushing with a toothbrush, use a moist gauze or foam swab Discontinue use of toothpaste if it is too astringent and dip toothbrush in bland rinse If there has been an oral infection, use a new toothbrush after infection has resolved If unable to tolerate brushing, seek assistance from nursing or dental staff 	t • C • F • U • R • R • B • B • a
End of Life	 Continue with basic and intensified mouth care plan, if possible Instead of moist gauze may use a foam brush soaked in CHX 	8 b

Discontinue flossing if:

• Gums bleed for longer than two minutes

Restart flossing if:

• Platelet count is >20x10⁹ cells/L, or as instructed by cancer care team

Discontinue brushing if:

• Gums bleed for longer than two minutes

Restart brushing if:

 Platelet count is >20x10⁹ cells/L, or as instructed by cancer care team

Bland rinse:

 1 teaspoon salt, 1 teaspoon baking soda, 4 cups of water

Lidocaine alternative:

 Dyclonine 0.5 or 1% rinse (5 mL every 6 to 8 hours, swish and swallow) as needed for pain

Patients with head and neck cancers:

- Brushing may not be appropriate in the area of tumour involvement
- Consult with a dentist
- Patients should be assessed for the use of daily fluoride tray

Patients with dentures:

- Remove dentures, plates and prostheses before brushing
- Brush and rinse dentures after meals and at bedtime
- Remove from mouth nightly (at least 8 hours per 24 hours) and soak in bland rinse
- Leave dentures out as much as possible during radiation therapy
- Patients who have had head and neck surgery should not wear dentures post-surgery unless assessed by a dental specialist or head and neck surgeon, to prevent

Rinsing

Basic	 Rinse the oral cavity with a bland rinse vigorously, at least twice a day to maintain mouth moisture, remove the remaining debris and toothpaste, and reduce the accumulation of plaque and infection Use a bland rinse to increase oral clearance for oral hygiene maintenance and improved patient comfort. Following emesis, rinse with bland rinse immediately to neutralize the mouth If allergic to lidocaine, dyclonine 0.5 or 1% rinse (5 mL every 6 to 8 hours, swish and swallow) may be used as needed for pain
Intensified	 Rinse in place of brushing if patient is unable to brush Seek dental care where possible for removing plaque In addition to rinsing twice a day, encourage rinsing every 1 to 2 hours while awake and every 4 hours through the night if awake, to minimize complications of decreased saliva If unable to clean using moist gauze, or foam swab, consider rinsing via syringe if platelet count >20x10⁹ cells/L
End of Life	 Continue with basic and intensified mouth care plan Consider sialagogues in instances of dry mouth for pharmacotherapy relief (pilocarpine, and anethole trithione)

Moisturizing the Oral Cavity

Basic	 Moisturize the mouth with water, artificial saliva products, or other water soluble lubricants Apply lubricant after each cleaning, at bedtime, and as needed. Water-based lubricant needs to be applied more frequently Frequent rinsing as needed with basic mouth rinse Patients may suck on xylitol lozenges (up to 6 grams a day), xylitol containing popsicles, or xylitol containing gum
Intensified	 Continue with basic mouth care plan with increased frequency and intensity Increase frequency of bland mouth rinse to every hour
End of Life	 Continue with basic mouth care plan with increased frequency and intensity, as needed Use a steam vaporizer at night May use a cool mist humidifier at night, but use should be weighed against the risk for fungal infection

Lip Care

Basic	 To keep lips moist and avoid chapping and cracking, use water soluble lubricants, lanolin (wax-based), or oil based lubricants (mineral oil, cocoa butter) Water soluble lubricants should be used inside and outside the mouth, and may also be used with oxygen (e.g. products compounded with Glaxal base or Derma base) Apply lubricant after each cleaning, at bedtime, and as needed. Water-based lubricants need to be applied more frequently
Intensified	Continue with basic mouth care plan with increased frequency and intensity
End of Life	 Continue with basic mouth care plan with increased frequency and intensity, as needed May use a cool mist humidifier at night, but use should be weighed against the risk for fungal infection

Miscellaneous

Basic	 Dental evaluation and treatment as indicated prior to cancer therapy is desirable to reduce risk for local and systemic infections from odontogenic sources for hematologic, solid or head and neck cancers
Intensified	Continue with basic mouth care plan with increased frequency and intensity
End of Life	Continue with basic mouth care plan with increased frequency and intensity, as needed

Patients with dentures:

- After removing dentures, rinse mouth thoroughly with rinse solution
- Brush and rinse dentures after meals and at bedtime
- Rinse with rinsing solution before placing in mouth
- Remove from mouth nightly (at least 8 hours per 24 hours) and soak in rinsing solution

Bland rinse:

• 1 teaspoon salt, 1 teaspoon baking soda, 4 cups of water

Avoid:

- Club soda due to the presence of carbonic acids
- Commercial mouthwashes with hydroalcoholic base or astringent properties

Avoid:

- Glycerin or lemon-glycerin swabs as they dry the mouth
- Acidic or minty mouth products, if they burn

Avoid:

- Touching any lip lesions
- Oil based lubricants on the inside of the mouth
- Petroleum based products

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