MUCOSAL ULCERATIONS

CHI Formulary Development Project

INDICATION UPDATE

ADDENDUM- October 2023

To the CHI Original Mucosal Ulcerations Clinical Guidance- Issued June 2020

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Related Documents

Related SOPs

- IDF-FR-P-02-01-IndicationsReview&IDFUpdates
- IDF-FR-P-05-01-UpdatedIndicationReview&IDFUpdates

Related WI:

- IDF-FR-WI-01-01SearchMethodologyGuideForNewIndications

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Executive Summary

A mouth ulcer is a sore that can develop anywhere within your mouth[1]. These sores typically display colors like red, yellow, or white and can occur individually or in multiples[1]. They can emerge on your gums, tongue, palate, inner cheeks, and inner lips. These ulcers often cause discomfort, making eating, drinking, and speaking unpleasant[1]. They are not sexually transmitted and cannot be contracted or transmitted through activities like kissing or sharing food[1].

Generally, mouth ulcers are harmless and tend to resolve on their own within one to two weeks[1]. However, specific types of mouth sores might indicate underlying health issues, such as viral infections, autoimmune disorders, or gastrointestinal problems[1]. Various categories of mouth ulcers include canker sores, oral lichen planus, leukoplakia, erythroplakia, oral thrush, and mouth cancer[1]. Identifying mouth ulcers is usually straightforward, as they manifest as sores that are red around the edges and have a white, yellow, or gray center[1].

Mouth ulcers result from a range of causes, including minor injuries from dental procedures, accidental biting of the cheek or tongue, allergic reactions to certain bacteria, wearing braces, using abrasive toothpaste, consuming acidic foods, hormonal fluctuations during menstruation, stress, and lack of sleep[1]. Moreover, certain health conditions like autoimmune diseases, vitamin deficiencies, viral, bacterial, or fungal infections[1]. Common mouth ulcer treatments include antiseptic gels or mouth rinses, steroid ointments like triamcinolone, immunosuppressants (in severe cases)[1].

25% of the global population are thought to be affected by recurrent aphthous ulcers, one of the most common causes of oral ulcers; and the prevalence of oral ulcers in children has been reported as 9%[2]. A study was conducted in KSA over 3 years and published in 2009 in the Annals of Saudi Medicine, where 2552 dental outpatients were investigated clinically for the presence of oral mucosal conditions. 15.0% (383 out of 2,552) of dental outpatients had oral mucosal lesions, with women making up 57.7% of these cases. Patients aged 31 to 40 were the most affected, while those over 61 were the least affected[3].

CHI issued Mucosal Ulcerations clinical guidelines after thorough review of renowned international and national clinical guidelines in June 2020. Updating clinical practice guidelines (CPGs) is a crucial process for maintaining the validity of recommendations.

This report functions as an addendum to the prior CHI Mucosal Ulcerations clinical guidance and seeks to offer guidance for the effective management of Mucosal Ulcerations. It provides an **update on the Mucosal Ulcerations Guidelines** for CHI Formulary with the ultimate objective of updating the IDF (CHI Drug Formulary) while

addressing **the most updated best available clinical and economic evidence related to drug therapies.**

There are no updated versions of previously reviewed guidelines that were issued, nor were **new guidelines added to the report**.

After carefully examining clinical guidelines and reviewing the SFDA drug list, there are no new drugs to be added to the CHI formulary, and there are no new drugs approved by the FDA. Three drugs are no longer SFDA-registered, and it is advisable to delist them from CHI formulary: Tiaprofenic acid, Hydrogen peroxide, and Acemetacin.

All recommendations are well supported by reference guidelines, Grade of Recommendation (GoR), Level of Evidence (LoE) and Strength of Agreement (SoA) in all tables reflecting specific drug classes' role in Mucosal Ulcerations therapeutic management.

Below is a table summarizing the major changes based on the different Mucosal Ulcerations guidelines used to issue this report:

Table 1. General Recommendations for the Management of Mucosal Ulcerations

Management of Mucosal Ulcerations		
General Recommendations	**Level of Evidence/ Grade of Recommendation**	**Reference**
Initial management if ulceration has been present for 3 weeks or more		
Refer the patient for urgent care to investigate potential dysplasia or malignancy.	N/A	Management of Acute Dental Problems (SDcep, 2013)[4]
Initial management if ulceration has been present for less than 3 weeks		
If ulceration is recurrent and self-limiting, advise the patient to use 0.2% chlorhexidine mouthwash and to seek non-urgent dental care.	N/A	Management of Acute Dental Problems (SDcep, 2013)[4]
For children, recommend optimal analgesia, soft diet and advise that ulcers are likely to resolve within 1-2 weeks.	N/A	Management of Acute Dental Problems (SDcep, 2013)[4]
If there are multiple ulcers present, advise the patient to seek non-urgent dental	N/A	Management of Acute Dental

care. However, if the patient is also systemically unwell, advise them to seek urgent medical care.		Problems (SDcep, 2013)[4]
If a single ulcer appears not to have been caused by trauma or ill-fitting dentures, advise the patient to use 0.2% chlorhexidine mouthwash until symptoms resolve. Keep dentures out where possible and seek non-urgent dental care.	N/A	Management of Acute Dental Problems (SDcep, 2013)[4]
Do not prescribe antibiotics unless there are signs of spreading infection, systemic infection, or for an immunocompromised patient.	N/A	Management of Acute Dental Problems (SDcep, 2013)[4]
If the ulcer fails to heal within a week, to see a dentist within 7 days recommend optimal analgesia, including prescription of topical analgesics.	N/A	Management of Acute Dental Problems (SDcep, 2013)[4]
Simple Mouthwashes as Treatment Options		
Rinse mouth with a salt solution prepared by dissolving half a teaspoon of salt in a glass of warm water to relieve pain and swelling.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
For children and adults: Sodium Chloride Mouthwash. Dilute with an equal volume of warm water. Spit out mouthwash after rinsing.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Antimicrobial Mouthwashes as Treatment Options		
For children and adults (above 7 years of age): chlorhexidine mouthwash, 0.2%: Rinse mouth for 1 minute with 10 ml twice daily.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Hydrogen Peroxide Mouthwash, 6%: Rinse mouth for 2 minutes with 15 ml diluted in half a glass of warm water three times daily.	N/A	Prevention and Treatment of Periodontal

		Diseases (SDcep, 2014)[5]
Doxycycline Dispersible Tablets, 100 mg: 1 tablet to be dissolved in water and rinsed around the mouth for 2 minutes four times daily for three days at the onset of ulceration. Doxycycline is not licensed for use in children under 12 years.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Local Analgesics as Treatment Options		
Benzydamine Mouthwash, 0.15%: Rinse or gargle using 15 ml every 1½ hours as required.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Benzydamine Oro mucosal Spray, 0.15%: • 6 months- 1 spray per 4 kg 5 years body weight (max. 4 sprays) every 1½ hours. • 6-17 years 4 sprays every 1½ hours • In adults and children of 12 years and over, up to 8 sprays of benzydamine	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Lidocaine • Ointment, 5% [For children and adults]: Rub sparingly and gently on affected areas. • Spray, 10%: Apply as necessary with a cotton bud.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Topical Corticosteroids as Treatment Options		
Beclomethasone dipropionate inhaler (Clenil Modulite®) sprayed twice daily onto the affected site.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]
Betamethasone Soluble Tablets, 500 micrograms: 1 tablet dissolved in 10 ml water as a mouthwash four times daily. Spit out mouthwash after rinsing. It is not appropriate for children < 12 years.	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]

Hydrocortisone Oro mucosal Tablets, 2.5 mg: 1 tablet dissolved next to lesion four times daily	N/A	Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5]

At the end of the report, a key recommendation synthesis section is added highlighting the latest updates in **Mucosal Ulcerations clinical and therapeutic management**.

Section 1.0 Summary of Reviewed Clinical Guidelines and Evidence

This section is divided into two parts: one part includes recommendations from **updated versions of guidelines** mentioned in the previous CHI Mucosal Ulcerations report, and one part includes **newly added guidelines** that have helped generate this report.

1.1 Revised Guidelines

This part contains the updated versions of the guidelines mentioned in the June 2020 CHI Mucosal Ulcerations Report and the corresponding recommendations:

Table 2. Clinical Guidelines Requiring Revision

Guidelines Requiring Revision	
Old Versions	**Updated Versions**
Section 1.1 Prevention and Treatment of Periodontal Diseases in Primary Care Scottish Dental Clinical Effectiveness Programme [SDcep 2014][5]	1.1.1 Scottish Dental Clinical Effectiveness Programme (SDCEP) Drug Prescribing for Dentistry (Third Edition) (2016)[6]
Section 1.2 Scottish Dental Clinical Effectiveness Programme [SDcep 2013] Management of Acute Dental Problems Guidance for healthcare professionals[4]	N/A*

*: No updated versions available

1.1.1 Scottish Dental Clinical Effectiveness Programme (SDCEP) Drug Prescribing for Dentistry (Third Edition) (2016)

Please refer to Section 1.1 of CHI Mucosal Ulcerations Report.

There are no new updates. The recommendation statements related to the treatment of mucosal ulceration remained unchanged[6].

1.1.2 Scottish Dental Clinical Effectiveness Programme [SDcep 2013] Management of Acute Dental Problems Guidance for healthcare professionals

Please refer to Section 1.2 of CHI Mucosal Ulcerations Report.

There are no new updates. The recommendations of this guideline remain unchanged[4].

1.2 New Guidelines

This part typically includes the added guidelines to the previous CHI Mucosal Ulcerations report, along with their recommendations.

However, there are no new guidelines to be added to this report.

Section 2.0 Drug Therapy in Mucosal Ulcerations

This section comprises three subsections: the first one contains the newly recommended drugs, the second one covers drug modifications, and the third one outlines the drugs that have been withdrawn from the market.

2.1 Additions

There are no new drugs added to the treatment of Mucosal Ulcerations. The drugs used in the management of Mucosal Ulcerations are still the same.

2.2 Modifications

There are no modifications from the previous CHI Mucosal Ulcerations Report.

2.3 Delisting

The medications below are no longer SFDA registered[7], therefore, it is advisable to delist the following drugs from CHI formulary. *Please refer to **Drug Therapy in Mucosal Ulcerations - Section 2** of CHI Mucosal Ulcerations original clinical guidance*

- Tiaprofenic acid
- Hydrogen peroxide
- Acemetacin

Section 3.0 Key Recommendations Synthesis

- Initial management (Management of Acute Dental Problems (SDcep, 2013)[4])
  - If ulceration has been present for 3 weeks or more, refer the patient for urgent care to investigate potential dysplasia or malignancy.
  - When ulceration has been present for less than 3 weeks:
    - If ulceration is recurrent and self-limiting, advise the patient to use 0.2% chlorhexidine mouthwash and to seek non-urgent dental care.
    - For children, recommend optimal analgesia, soft diet and advise that ulcers are likely to resolve within 1-2 weeks.
    - If there are multiple ulcers present, advise the patient to seek non-urgent dental care. However, if the patient is also systemically unwell, advise them to seek urgent medical care.
    - If ulceration is due to ill-fitting dentures, advise the patient to use 0.2% chlorhexidine mouthwash, to keep dentures out where possible and to seek non-urgent dental care.
    - Do not prescribe antibiotics unless there are signs of spreading infection, systemic infection, or for an immunocompromised patient.
    - If a single ulcer appears not to have been caused by trauma, advise the patient to use 0.2% chlorhexidine mouthwash until symptoms resolve or if the ulcer fails to heal within a week, to see a dentist within 7 days recommend optimal analgesia, including prescription of topical analgesics.
    - Note: Chlorhexidine mouthwash is not suitable for children under 7 years old.
- Simple Mouthwashes (Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5])
  - Advise the patient to rinse their mouth with a salt solution prepared by dissolving half a teaspoon of salt in a glass of warm water to relieve pain and swelling. Alternatively, compound sodium chloride mouthwashes made up with warm water can be prescribed.
  - An appropriate regimen for children and adults: Sodium Chloride Mouthwash. Dilute with an equal volume of warm water. Spit out mouthwash after rinsing.

- Antimicrobial Mouthwashes (Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5])
    - An appropriate regimen is a choice for children and adults: chlorhexidine mouthwash, 0.2%: Rinse mouth for 1 minute with 10 ml twice daily.
    - Hydrogen Peroxide Mouthwash, 6%: Rinse mouth for 2 minutes with 15 ml diluted in half a glass of warm water three times daily.
    - Doxycycline Dispersible Tablets, 100 mg: 1 tablet to be dissolved in water and rinsed around the mouth for 2 minutes four times daily for three days at the onset of ulceration. Doxycycline is not licensed for use in children under 12 years and doxycycline dispersible tablets are not licensed for oral ulceration in adults or children.
- Local Analgesics (Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5])
    - Benzydamine Mouthwash, 0.15%: Rinse or gargle using 15 ml every 1½ hours as required.
    - Benzydamine Oro mucosal Spray, 0.15%: 4 sprays onto affected area every 1½ hours. In adults and children of 12 years and over, up to 8 sprays of benzydamine Oro mucosal spray can be applied at any one time. For children: ≤12 years Not recommended for use.
    - For children: Benzydamine Oro mucosal Spray, 0.15% 6 months- 1 spray per 4 kg 5 years body weight (max. 4 sprays) every 1½ hours 6-17 years 4 sprays every 1½ hours.
    - Lidocaine Ointment, 5% [For children and adults]: Rub sparingly and gently on affected areas.
    - Lidocaine Spray, 10%: Apply as necessary with a cotton bud.
- Topical Corticosteroids (Prevention and Treatment of Periodontal Diseases (SDcep, 2014)[5])
    - Beclomethasone dipropionate inhaler (Clenil Modulite®) sprayed twice daily onto the affected site is suitable for tongue lesions and accessible areas.
    - Betamethasone Soluble Tablets, 500 micrograms: 1 tablet dissolved in 10 ml water as a mouthwash four times daily. spit out mouthwash after rinsing. For children < 12 years, not appropriate
    - Hydrocortisone Oro mucosal Tablets, 2.5 mg: 1 tablet dissolved next to lesion four times daily.

- Clenil Modulite®, 50 micrograms/ metered inhalation (beclomethasone pressurized inhalation, CFC-free) [For children ≥2 years and adults]: 1-2 puffs directed onto ulcers twice daily.

Section 4.0 Conclusion

This report serves as **an annex to the previous CHI Mucosal Ulcerations report** and aims to provide recommendations to aid in the management of Mucosal Ulcerations. It is important to note that these recommendations should be utilized to support clinical decision-making and not replace it in the management of individual patients with Mucosal Ulcerations. Health professionals are expected to consider this guidance alongside the specific needs, preferences, and values of their patients when exercising their judgment.

Section 5.0 References

1. Mouth Ulcers: Types, Causes & Treatment. Accessed August 29, 2023. https://my.clevelandclinic.org/health/diseases/21766-mouth-ulcer
2. Oral Ulceration (Causes, Symptoms, and Treatment) | Patient. Accessed August 29, 2023. https://patient.info/doctor/oral-ulceration
3. Al-Mobeeriek A, AlDosari AM. Prevalence of oral lesions among Saudi dental patients. *Ann Saudi Med*. 2009;29(5):365-368. doi:10.4103/0256-4947.55166
4. *Management of Acute Dental Problems Guidance for Healthcare Professionals*.; 2013.
5. *Prevention and Treatment of Periodontal Diseases in Primary Care Dental Clinical Guidance Scottish Dental Clinical Effectiveness Programme SDcep*.; 2014.
6. *Scottish Dental Clinical Effectiveness Programme SDcep*.; 2016.
7. SFDA Drug List J. SFDA Drug List . Published 2023. Accessed June 20, 2023. https://www.sfda.gov.sa/en/drugs-list

Section 6.0 Appendices

Appendix A. Prescribing Edits Definition

I. Prescribing Edits (ensure consistent use of abbreviations, e.g., CU, ST)

Some covered drugs may have additional requirements, rules or limits on coverage. These requirements and limits may include:

Prescribing edits Tools	Description
AGE (Age):	Coverage may depend on patient age
CU (Concurrent Use):	Coverage may depend upon concurrent use of another drug
G (Gender):	Coverage may depend on patient gender
MD (Physician Specialty):	Coverage may depend on prescribing physician's specialty or board certification
PA (Prior Authorization):	Requires specific physician request process
QL (Quantity Limits):	Coverage may be limited to specific quantities per prescription and/or time period
ST (Step Therapy):	Coverage may depend on previous use of another drug
EU (Emergency Use only):	This drug status on Formulary is only for emergency use
PE (Protocol Edit):	Use of drug is dependent on protocol combination, doses and sequence of therapy

II. Adult and Pediatric Quantity Limit?

This is either the adult or pediatric maximum amount of a drug that can be administered per day based on a maximum daily dose. If there is no clinical evidence supporting the quantity limit for that relevant indication, this column will be left as Blank.

III. What information is available in the notes?

"Notes" section provides details of the prescribing edits, extra important drug information and special warning and precautions.

IV. Drug interactions

- A: No known interaction
- B: No action needed
- C: Monitor therapy
- D: Consider therapy modification
- X: Avoid combination

V. Defined Daily Dose

The Defined Daily Dose (DDD) is to be set based on the WHO recommendations https://www.whocc.no/ddd/definition_and_general_considera/

VI. REMS

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

Appendix B. Mucosal Ulcerations Scope

Comparison of the 2020 and the 2023 Report

2020	Changes Performed	2023	Rationale
Section 1.0 Mucosal Ulcerations Clinical Guidelines			
Prevention and Treatment of Periodontal Diseases in Primary Care Scottish Dental Clinical Effectiveness Programme [SDcep 2014][5]	N/A	N/A	
Scottish Dental Clinical Effectiveness Programme [SDcep 2013] Management of Acute Dental Problems Guidance for healthcare professionals [4]	N/A	N/A	
	Missing	N/A	

Appendix C. PubMed Search Strategy: MeSH Terms and Boolean Operators

The following is the result of the PubMed search conducted for guideline search:

Query	Filters	Search Details	Results
((((((Oral Ulcer[MeSH Terms]) OR (Oral Ulcers[Title/Abstract])) OR (Ulcer, Oral[Title/Abstract])) OR (Ulcers, Oral[Title/Abstract])) OR (Mouth Ulcer[Title/Abstract])) OR (Mouth Ulcers[Title/Abstract])) OR (Ulcer, Mouth[Title/Abstract])) OR (Ulcers, Mouth[Title/Abstract])	Guideline, in the last 5 years, English	("oral ulcer"[MeSH Terms] OR "oral ulcers"[Title/Abstract] OR "ulcer oral"[Title/Abstract] OR "ulcers oral"[Title/Abstract] OR "mouth ulcer"[Title/Abstract] OR "mouth ulcers"[Title/Abstract] OR "ulcer mouth"[Title/Abstract] OR "ulcers mouth"[Title/Abstract]) AND ((y_5[Filter]) AND (guideline[Filter]) AND (english[Filter]))	2

Appendix D. Treatment Algorithm