Clinical Sub-Group to support the delivery of an Expanded Role for Community Pharmacy

Common Conditions Service Protocol Cold Sores (Final)

V1.2 26/09/2025

This protocol does not impede the sale and supply of medicines 'over the counter' where this legal route of supply is relevant

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1. Critical Elements

1.1 Protocol Version
Version 1.2
1.2 Protocol Authors
Clinical Sub-Group to support the delivery of an Expanded Role for Community Pharmacy (See Appendix A for membership)
• Pharmacists wishing to deliver this service must: 1. Complete the mandatory Common Conditions Service training. Training can be accessed on the Irish Institute of Pharmacy website. 2. Adhere to the information and recommendations included in the Clinical Protocol for this common condition, and always ensure that they are following the current version of the protocol. Current versions of the Clinical Protocols can be accessed on the HSE website. 3. Comply with legislation in place that relates to delivery of the service and any associated guidance from the PSI. • NOTE: Locum pharmacists employed on a temporary basis who have successfully completed the training may be authorised to provide the service. They must be able to produce a record of their training upon request.

2. Clinical Criteria

2.1 Clinical condition for use of the protocol and differential diagnosis.

Cold Sores

Background

Cold sores are usually small, fluid-filled blisters around the mouth and lips that are caused by the herpes simplex virus (HSV). The virus is very common, and most individuals are exposed to the cold sore virus when they are young after close contact with someone who has a cold sore. Cold sores usually heal without treatment within ten days after the initial outbreak (primary infection). Following resolution of a cold sore, the virus remains dormant under the skin and can erupt again with new cold sores (recurrent infection) typically in the same area and this recurrence can be triggered by, for example, at times of illness, exposure to sunshine and/or stress.

The virus is highly infectious and is transmitted by skin-to-skin contact, usually through a kiss from an infected individual i.e. someone with an active cold sore.

Signs and Symptoms

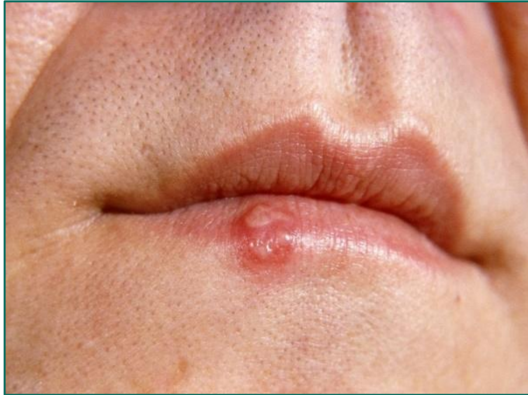
Small, fluid-filled blisters are the main HSV symptom in adults and children, particularly on the lips (herpes labialis). Cold sores usually start with a tingling, itching or burning feeling (prodromal phase). Over 48 hours, blisters may appear, weep and usually crust over into a scab. Lymph nodes may be swollen and tender. Cold sores do not tend to leave a scar, however, there may be some scarring with recurrent episodes on the same area, which can be more evident in individuals with darker skin tones.

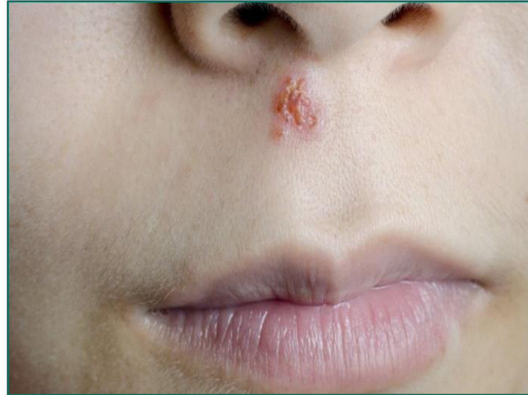
Many people experience occasional clinical recurrences with minimal symptoms that are self-limiting, and in such cases antiviral treatment may not be necessary.

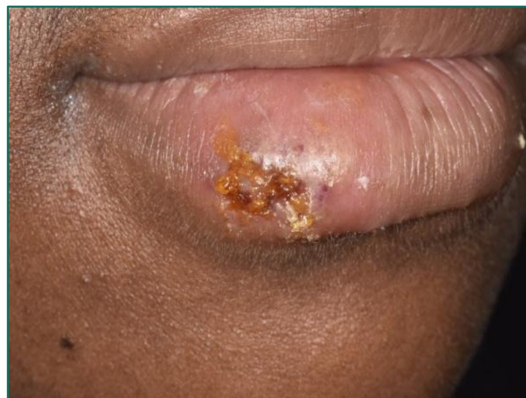
A number of triggers are associated with recurrent episodes of cold sores, but sometimes there is no identifiable cause. Examples of common triggers include:

- Sun exposure – The use of an SPF lip balm (minimum SPF 30) should be recommended in individuals with recurring cold sores.
- Cold weather exposure.
- Minor injuries or trauma to the affected area due to surgery.
- Common respiratory infections.
- Hormonal changes particularly in women due to menstruation, pregnancy or menopause.
- Emotional stress.

Symptoms which are also very common in children with cold sores include sore gums, sore throat and swollen glands, more saliva than normal, high temperature, headaches, and refusal to drink fluids. Cold sores can spread to a child’s fingers if a child sucks their fingers (herpetic whitlow). They can also spread to the eyes if the child touches an open sore and then rubs their eyes.


Small fluid-filled blisters appear (HSE A-Z)


The blisters can appear anywhere on the face (HSE A-Z)

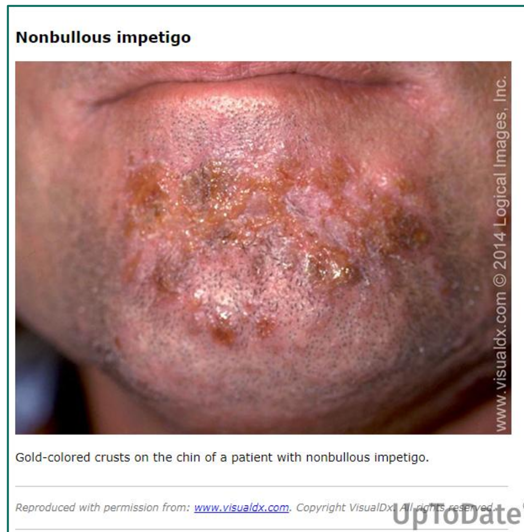

The blisters burst and crust over into a scab (HSE A-Z)

Differential Diagnosis:
Shingles (Herpes Zoster)
Herpes zoster infection is due to reactivation of the latent varicella zoster virus. Individuals will have been previously infected with the primary infection of varicella (chickenpox). The virus remains dormant in the sensory dorsal root ganglia for years before it is reactivated. The reactivated virus travels down sensory nerves to the skin and is usually localised to a specific nerve distribution. The shingles rash manifests in the dermatome, which is the area of skin innervated from the affected dorsal root ganglia. Herpes zoster can occur at any age but is usually more common in older people or individuals who are immunocompromised.

Herpes Zoster (UpToDate®)

Non-bullous impetigo

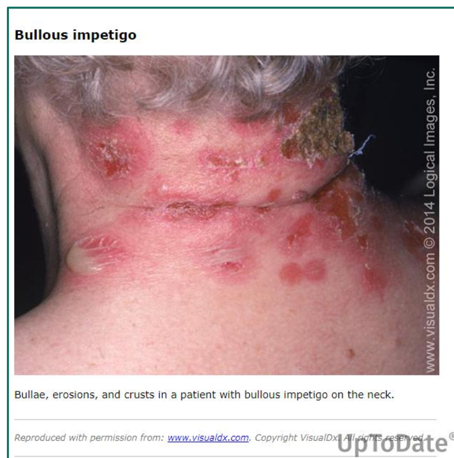
Non-bullous impetigo is the most common form of impetigo. It usually presents around the nose and mouth but may affect other extremities including the limbs and flexures. The symptoms of non-bullous impetigo begin with the appearance of small erythematous macule (a flat, discoloured area of skin). Vesicles (blisters) then appear as fluid filled lesions (less than 0.5cm in diameter). The blisters burst leaving behind thick, honey-coloured crusts typically around 2cm in diameter. Once the crusts dry, they leave a red mark which usually disappears within a few days or weeks, without leaving a scar. These lesions are not painful. There may be some itching in the area and individuals should be counselled to avoid scratching or touching the areas as they may spread the infection to other parts of the body (autoinoculation), and to others people. In more severe cases of infection symptoms may include swollen glands and fever.



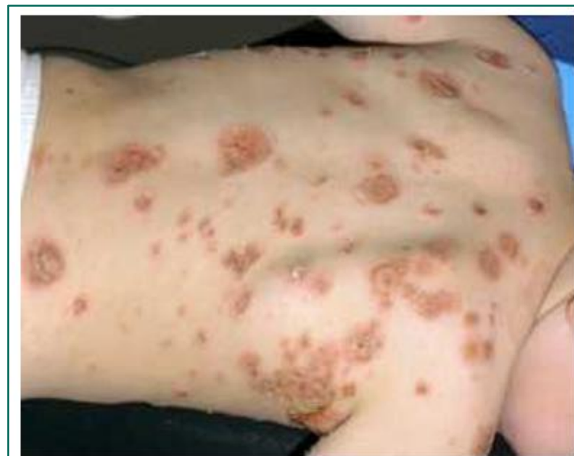
Nonbullous impetigo (UpToDate ®)

Bullous impetigo

In bullous impetigo, symptoms begin with the appearance of the bullae (large, flaccid, fluid filled blisters) which are usually 1cm to 2cm in diameter. These blisters are filled with yellow/clear fluid, spread rapidly, and may present with pain and itching in the affected area(s). It most commonly affects the trunk, neck, arms, and legs. Individuals are more likely to present with fever or swollen glands with this type of impetigo. Once the blisters burst, they leave a yellow crust which typically heals without scarring over days and weeks. Individuals should be counselled to avoid touching the area.



Bullous impetigo (UpToDate ®)


Widespread bullous impetigo over the back (HSE Antibiotic Prescribing)

Squamous cell carcinoma of the lip
Squamous cell carcinoma of the lip most often occurs in the lower lip region. It is more prevalent in outdoor workers with sun exposure. It can appear as a crusted lesion which closely resembles a crusted cold sore. Individuals with lesions on their lips which persist for longer than 14 days should be urgently referred to a Dental Practitioner or GP for further follow-up.

Squamous cell carcinoma on the lip (UpToDate®)

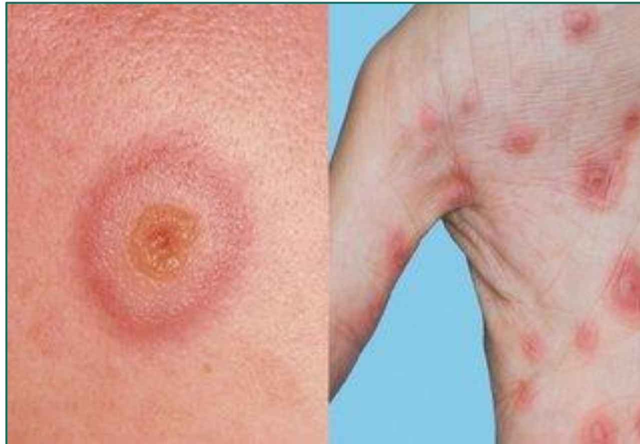
Complications of Cold Sores:
Gingivostomatitis
Clusters of blisters or sores may develop inside the mouth. Gingivostomatitis may occur as part of the primary HSV infection and less frequently with subsequent infections. The blisters may appear similar to ulcers and have a white to yellowish appearance inside the mouth and the gums may present as bleeding, red or swollen. It is more common in children but may also occur in adults.

Erythema multiforme
Erythema multiforme is a skin reaction that can be triggered by an infection, often the cold sore virus, or some medicines. Some people will get a cold sore a few days before the rash starts. It is usually mild and goes away in a few weeks but there is also a rare, severe form that can affect the mouth, genitals and eyes and can be life-threatening (erythema multiforme major). Erythema multiforme mainly affects adults under 40, but it can happen at any age. The rash starts suddenly and develops over a few days. It often starts on the hands or feet, and spreads to the limbs, upper body and face. The rash:

- starts as small red spots, which may become raised patches a few centimeters in size.
- often has patches with a dark red centre that may have a blister or crust, surrounded by a pale pink ring and a darker outermost ring – it can look like a bullseye and is often called a "target lesion".
- may be slightly itchy or uncomfortable.
- usually fades over 2 to 4 weeks.

In more severe cases, the patches may join together to form large, red areas that may be raw and painful.

See Section 2.4 for referral pathway.



Erythema multiforme (HSE A-Z)

2.2 Summary of Clinical Features

- Prodromal Phase – tingling, itching, or burning feeling on lip.
- Fluid-filled blisters may appear, weep and crust over into a scab.
- Swollen and tender glands.
- Other symptoms in children may include sore gums, sore throat and swollen glands, more saliva than normal, high temperature, headaches, and refusal to drink fluids.
- Clusters of blisters or sores may develop inside the mouth – known as Gingivostomatitis.

2.3 Inclusion criteria

2.3.1 CRITERIA FOR INCLUSION

- Informed consent given by an individual or parent/legal guardian for a child aged under 16 years.
- Herpes simplex virus infections of the skin, lips and face (recurrent herpes labialis).
- Individuals aged 1 month and older (corrected age for infants who are pre-term. The corrected age is the age based on the date they should have been born e.g. if a 10-month-old baby was born 2 months early, their corrected age is 8 months old).
- Pharmacists can **consider prescribing an initial supply of treatment <u>if clinically appropriate</u>**, while referring individuals who meet the criteria set out in **Section 2.4.4**.

2.4 Exclusion criteria and Referral Pathways

2.4.1 CRITERIA REQUIRING EMERGENCY REFERRAL TO HOSPITAL EMERGENCY DEPARTMENT/CONTACTING EMERGENCY SERVICES

- Individual is systemically very unwell, or showing symptoms of severe/life-threatening infection, or systemic sepsis: **Refer urgently to Emergency Department via ambulance.**

2.4.2 CRITERIA REQUIRING URGENT MEDICAL ASSESSMENT (TREATING SERVICE/GENERAL PRACTITIONER/GENERAL PRACTITIONER OUT OF HOURS/HOSPITAL EMERGENCY DEPARTMENT)

- Individuals under 1 month of age (corrected age for infants who are pre-term).
- Lesions involving the eye.
- Individual has moderate to severe immunocompromise due to underlying medical conditions or treatments.

2.4.3 CRITERIA REQUIRING REFERRAL TO GENERAL PRACTITIONER or OTHER RELEVANT MEDICAL PRACTITIONER

Note: Pharmacist prescribing not permitted

- Contraindications as specified in the medication Summary of Product Characteristics.
- Pregnancy or suspected pregnancy (refer to GP/treating obstetrician/gynaecologist).
- Signs of infection spreading.
- Symptoms not improving within 14 days, with or without treatment.
- Signs of secondary infection e.g. very painful or very swollen.
- Suspected gingivostomatitis – or refer to Dental Practitioner.
- Suspected erythema multiforme.
- Known hypersensitivity or adverse reaction to medication treatment options as included in Section 3.1, or any of the components within the formulation.

2.4.4 CRITERIA REQUIRING REFERRAL TO GENERAL PRACTITIONER or OTHER RELEVANT MEDICAL PRACTITIONER – INITIAL LIMITED SUPPLY*

***Pharmacists can consider prescribing an initial limited supply of treatment if clinically appropriate to mitigate the risk of delay in access to treatment. Treatment should be limited to the dose or time necessary for an individual to access the referral pathway.**

- Individual is immunocompromised due to underlying medical conditions or treatments (excluding those with moderate to severe immunocompromise: see Section 2.4.2).
- Recurrent problematic lesions or frequently recurrent infection (to ensure no underlying immunocompromise or another diagnosis).

2.5 Action to be taken where individual meets exclusion criteria, or treatment is not indicated, or if the individual/parent/legal guardian declines treatment

- If individual meets exclusion criteria, they should be referred or signposted as per the protocol (see Section 2.4).
- Advise individual/parent/legal guardian to seek medical advice if symptoms deteriorate.
- Signpost to available resources on HSE A-Z and the HSE app if appropriate.
- Follow record keeping procedures.

3. Details of medication

3.1 Name of medication, dose, and duration

Treatment Options & Formulary

Many individuals experience occasional self-limiting clinical recurrences with minimal symptoms and in such cases antiviral treatment may not be necessary. Advice on non-pharmacological treatment options should be provided to individuals (see Section 4).

Topical Treatment for Cold Sores

Drug	Children's Dose	Adult Dose	Duration	Notes
Aciclovir 5% w/w cream	Apply five times daily at approximately four hourly intervals omitting the night time application.	Apply five times daily at approximately four hourly intervals omitting the night time application.	Treatment should be continued for at least 4 days. If healing has not occurred, treatment may be continued for up to 10 days.	Should be applied as soon as possible, preferably during the earliest stages (prodrome or erythema). Treatment can also be started during the later (papule or blister) stages.

3.2 Summary of Product Characteristics including warnings, cautions, contraindications, interactions and side effects.

Visit the Health Products Regulatory Authority (HPRA) website for detailed drug information (summary of product characteristics and patient information leaflets). Dosing details, contraindications and drug interactions can also be found in the Irish Medicines Formulary (IMF) or other reference sources such as British National Formulary (BNF) / BNF for children (BNFC).

3.3 Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie

3.4 Procedure for the reporting and documentation of errors and near misses involving the medication including open disclosure.

PSI Advice on Medication Error Management:
https://www.psi.ie/practice-supports/practice-updates-and-learnings/advice-medication-error-management
PSI Open Disclosure:
Open Disclosure | PSI

3.5 Resources and equipment necessary for care under the protocol to be specified. This is dependent on the assessment requirements and best practice guidelines identified for the clinical condition.

- HSE National Consent Policy
- Chaperone Policy
- Patient Consultation Area
- Infection Prevention Control Measures
- Protecting Staff – Occupational Health

4. Patient/service-user care information

4.1 General Advice for Self-Care and Safety Netting

An individual should see their GP or other relevant Medical Practitioner if symptoms deteriorate, or persist for longer than 14 days, with or without treatment.

Non-pharmacological treatment options

Consider suitability of topical analgesics, mouthwash, and lip barrier preparations.

Treating cold sores at home

Individuals should be advised to:

- Drink lots of fluids (such as water or milk).
- Eat cool, soft foods.
- Avoid salty foods or citrus foods (these can make blisters sting).
- Wash their hands often with soap and warm water after touching the cold sore or applying cream to the cold sore.
- Wash their child's clothes separately if they have a cold sore.
- Avoid trigger factors, if possible, e.g. use of sunscreen or sunblock lip balm for people with recurrent infections triggered by sunlight.

In order to reduce the risk of autoinoculation and transmission to other people, individuals should be advised **NOT** to:

- Touch cold sores – except when they put on cold sore creams.
- Share anything that comes into contact with cold sores – such as cold sore creams, cutlery and towels.
- Kiss anyone if they have a cold sore.
- Engage in oral sex until the cold sore has completely healed.
- Let people with a cold sore kiss their baby or child to prevent the risk of neonatal herpes which is caused by the *Herpes simplex* infection spreading to newborn babies or infants. This can be fatal.

Childcare, school and contact play

A child can usually continue going to childcare and school if they have a cold sore and they are well enough to attend. Children should be supported to follow hygiene practices while the cold sore is weeping.

Children with cold sores should avoid playing, particularly participating in sports that involve skin-to-skin contact, with other children until:

- their cold sores have completely healed.
- any related symptoms have stopped (for example, fever).

It should be ensured that equipment such as gym equipment and mats are cleaned regularly and after use.

4.2 Medication information to be provided to the individual/parent/legal guardian using the authorised patient information leaflet if one is available.

- Signpost to available resources on HSE A-Z and the HSE app.
- Medication Patient Information Leaflets (PILs).

Key References

- HPRA https://www.hpra.ie/
- HSE Antibiotic Prescribing https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/
- HSE A-Z https://www2.hse.ie/conditions/
- HSE National Guideline on Oral Health – Supporting Smiles for Health and Social Care Professionals (and their teams) who support or provide oral care for adults
- UpToDate Epidemiology, clinical manifestations, and diagnosis of herpes simplex virus type 1 infection and related images https://www.uptodate.com/contents/epidemiology-clinical-manifestations-and-diagnosis-of-herpes-simplex-virus-type-1-infection

Appendix A – Clinical Sub-Group Membership

Core Membership

- Dr. Siobhán Ní Bhriain - HSE National Clinical Director Integrated Care (Chair)
- Dr. David Hanlon - HSE National Clinical Advisor Primary Care (Vice Chair)
- Ms. Ciara Kirke - HSE Clinical Lead National Medication Safety Programme
- Ms. Linda Fitzharris - HSE PCRS Head of Pharmacy
- Dr. Diarmuid Quinlan - Medical Director ICGP & GP
- Ms. Elaine Dobell - HSE General Manager, Office of National Clinical Director Integrated Care
- Ms. Marie Philbin - AMRIC Chief Pharmacist
- Mr. Jonathon Morrissey - Community Pharmacist
- Ms. Áine McCabe - Community Pharmacist
- Dr. Clíona Murphy – National Women and Infants Health Programme
- Ms. Sarah Clarke - Medicines Management Programme

General Membership as needed

- Ms. Aoife Doyle - HSE National Clinical Lead for Ophthalmology
- Prof. Anne Marie Tobin - HSE National Clinical Lead for Dermatology
- Dr. Eavan Muldoon - HSE National Clinical Lead for Infectious Diseases
- Dr. Seán O'Dowd - HSE National Clinical Lead for National Dementia Office representing National Clinical Programme for Neurology on behalf of Prof. Sinéad Murphy
- Ms. Ruth Hoban - HSE West Assistant Director of Nursing and Midwifery for Nurse Prescribing on behalf of Dr. Geraldine Shaw
- Prof. Fiona Lyons - HSE National Clinical Lead for Sexual Health
- Ms. Caoimhe Gleeson - HSE National Office for Human Rights and Equality Policy
- Dr. Andrew Bolas - Assistant National Oral Health Lead
- Dr. Myra Herlihy - Assistant National Oral Health Lead Special Care and Training

Cold Sores CSG Working Group

- Dr. David Hanlon - HSE National Clinical Advisor Primary Care (Vice Chair)
- Ms. Ciara Kirke - HSE Clinical Lead National Medication Safety Programme
- Ms. Marie Philbin - AMRIC Chief Pharmacist
- Dr. Andrew Bolas - Assistant National Oral Health Lead
- Dr. Myra Herlihy - Assistant National Oral Health Lead Special Care and Training
- Mr. Jonathon Morrissey - Community Pharmacist

- Ms. Áine McCabe - Community Pharmacist