Lidocaine 5% medicated plaster (Versatis®) reimbursement

Questions and Answers for Healthcare Professionals

1) What is lidocaine 5% medicated plaster (Versatis®) and what is it used for?

Lidocaine 5% medicated plaster (Versatis®) is an adhesive hydrogel plaster containing the local anaesthetic lidocaine. It is indicated for the local relief of nerve pain that may occur after a previous herpes zoster (shingles) infection. Localised symptoms such as burning, shooting or stabbing pain are associated with this type of nerve pain.

2) How should lidocaine 5% medicated plaster (Versatis®) be used?

After the healing of shingles, the plaster should be applied to the painful area once daily for up to 12 hours within a 24 hour period. The minimum number of plasters that provides effective pain relief should be used. The lidocaine 5% medicated plaster (Versatis®) may be cut to size with scissors before removing from the liner to fit the affected area.

3) Why is the HSE introducing changes to the reimbursement of lidocaine 5% medicated plaster (Versatis®)?

The Medicines Management Programmes (MMP) has reviewed the evidence supporting the use of lidocaine 5% medicated plaster (available on www.hse.ie/yourmedicines). This report highlighted that the clinical evidence to support the use of lidocaine 5% medicated plaster (Versatis®) for PHN is limited due to lack of comparative data and short follow-up periods and its value is uncertain for all other types of pain.

Also, recent prescribing database analysis suggests the annual expenditure under the Community Drugs Schemes (CDS) exceeded **€30 million per annum** with over 25,000 in receipt of this medicine in 2016.

The new changes are aligned with best practice recommendations to ensure appropriate use of this product for the licensed indication.

4) How will patients be deemed eligible for reimbursement under this initiative?

Reimbursement will be approved based on information provided by the patients' clinician in relation to the indication for treatment. If reimbursement is sought for an unlicensed indication this information can also be provided through the online application (Exceptional Circumstances).

- **Reimbursement for post-herpetic neuralgia (PHN)**

Where the application is for the treatment of **PHN**, the name and date of antiviral prescribed is required and reimbursement will be approved.

- **Reimbursement for indications <u>other</u> than post-herpetic neuralgia (PHN)**

Where the application is for the treatment of **other types of neuropathic pain**, the online application will require information including the patient's diagnosis, location of pain, history of past and current treatments and any extenuating circumstances. This will be reviewed by the Medicines Management Programme (MMP) before a decision is made and communicated through the Application Suite to the clinician. Approval status can also be checked by the pharmacy on the Pharmacy Application Suite (outlined in question 7).

5) If a patient under my care is approved for reimbursement, how long can they receive treatment for?

Once reimbursement is authorised, there is no limit on the duration of treatment and no further applications will be required.

6) How will prescribers submit this information?

This information can be submitted by the patients' clinician through the online **Application Suite** by following the steps below on www.PCRS.ie.

Hospital Clinicians > Online Services > Services for Hospitals > Lidocaine 5% Medicated Plaster Reimbursement Application

GPs > Online Services > Services for General Practitioners only > GP Application Suite

7) How will Clinicians and Pharmacists review eligibility status?

Eligibility can be confirmed and monitored through the Application Suite and the Pharmacy Application Suite by following the steps below on www.PCRS.ie

Access for GPs

Online services > Services for General Practitioners only > GP Application Suite > Eligibility Confirmation

Access for Pharmacists

Online services > Services for Pharmacists only > Pharmacy Application Suite > Eligibility Confirmation

8) When did changes to reimbursement of lidocaine 5% medicated plaster (Versatis®) come into effect?

The changes to reimbursement came into effect on **1 September 2017** for new patients initiated on lidocaine 5% medicated plaster (Versatis®) and on **1 December 2017** for established patients on lidocaine 5% medicated plaster (Versatis®) prior to September 2017.

Currently, reimbursement will not be authorised without completion of the online approval process.

9) How will claims for lidocaine 5% medicated plaster (Versatis®) be processed?

Pharmacies can dispense and claim for lidocaine 5% medicated plaster (Versatis®) for approved patients electronically using the product GMS code, submitting in the normal manner with monthly claims.

Claims submitted for patients who are not approved will not be paid.

10) What alternative treatment(s) are available for non-PHN pain?

Alternative treatment(s) will depend on the type of pain. The use of oral analgesics may be suitable (e.g. paracetamol and/or non-steroidal anti-inflammatory drug [NSAID]). For soft tissue, muscular and/or rheumatic type pain a topical NSAID gel (e.g. diclofenac 1%) may be a suitable alternative.

11) What is the appeals process for lidocaine 5% medicated plaster (Versatis®)?

An appeals process is in place if necessary following a negative reimbursement decision from the online application process. Appeals can be sent directly to the MMP at mmp@hse.ie or by post to Prof Michael Barry (Clinical Lead, MMP), Department of Pharmacology and Therapeutics, Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8. Appeals must be made by the patient's clinician and should include any additional information to support the unmet clinical need for lidocaine 5% medicated plaster (Versatis®) based on failure of other treatment options. Appeals are reviewed on a case-by-case basis reviewing the information provided in the initial online application and the information in the appeal submission to the MMP. A letter outlining the final reimbursement decision is communicated back to the clinician.