Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5 an M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Guthán: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

10th August 2017

Circular 032/17

Reimbursement of Lidocaine 5% Plasters (Versatis®) effective 1st September 2017

Dear Doctor,

The purpose of this letter is to notify you of a recommendation of the HSE Medicines Management Programme (MMP) which has been accepted by the HSE in relation to individual approval of Lidocaine 5% medicated plasters (Versatis®) for specific patients i.e. those with post – herpetic neuralgia (PHN).

In this regard, please find enclosed a letter from Prof Michael Barry, Clinical Lead for the Medicines Management Programme outlining the recommendation in some detail and some FAQs for healthcare professionals.

The HSE will be implementing this recommendation from 1st September 2017. If you believe that any of your patients should receive reimbursement support for Lidocaine 5% plasters and they have previously had Shingles (Herpes Zoster), you can register specific patients for reimbursement support through the Special Drug Request section on the GP application suite.

To register specific patients for individual reimbursement support, please provide the following details online:

1. GMS number or Drugs Payment Scheme (DPS) Number
2. Patient Diagnosis – PHN or Other
3. If Antiviral Therapy has been used and when.
4. Exceptional Circumstances outside of the licensed indication.

All newly initiated patients on this treatment for PHN must be individually registered. When registered under PHN, approval is real-time and the patient will be approved for three months of reimbursement support.

Where the application is under Exceptional Circumstances, the application will be reviewed by the MMP before a decision is made and communicated through the application suite to the GP.

For patients currently prescribed this treatment, they will continue to access reimbursement support until 30th November 2017, after which time, an approval under Exceptional Circumstances should have been registered if you believe it necessary for your patient.

Your cooperation with this important HSE initiative is appreciated.

Yours faithfully,

Anne Marie Hoey

Anne Marie Hoey
Primary Care Reimbursement & Eligibility

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Preferred Drugs
THE RIGHT CHOICE, RIGHT NOW.
MEDICINES MANAGEMENT PROGRAMME

Re: Lidocaine 5% medicated plaster (VERSATIS®)

31 July 2017

Dear Colleagues,

Lidocaine 5% medicated plaster (Versatis®) is licensed for **the symptomatic relief of neuropathic pain associated with previous herpes zoster infection** known as post-herpetic neuralgia (PHN) in adults. It is a local anaesthetic agent which is applied directly to the affected area after the healing of herpes zoster (shingles) infection.

The Medicines Management Programmes (MMP) recently published a Prescribing and Cost Guidance report which highlighted that the clinical evidence to support the use of lidocaine 5% medicated plaster for PHN is limited due to lack of comparative data and its value is uncertain for all other types of pain.

Despite the limited clinical evidence, utilisation of this medication has increased over the last 5 years and there were over 25,000 patients in receipt of this medication at the end of 2016 with total expenditure exceeding €30 million.

The MMP recommends that the prescribing of lidocaine 5% medicated plaster should be restricted to patients with a diagnosis of PHN to ensure evidence based use of this medication.

Following the MMP review and based on best practice recommendations, the Primary Care Reimbursement Service (PCRS) are introducing changes to the reimbursement of lidocaine 5% medicated plaster from 1 September 2017. This process will support appropriate use of this medication while ensuring those with an indication of PHN continue to have access to this treatment.

The MMP has prepared "Tips and Tools" (attached) to guide appropriate use and offer topical treatment alternatives for both PHN and other types of pain. Further information including the full evaluation report, a summary report and information for healthcare professionals and patients are also available on the MMP website (www.hse.ie/yourmedicines).

We welcome your on-going feedback and support for our prescribing initiatives.

With best wishes,

Prof Michael Barry,
National Clinical Lead, Medicines Management Programme

Lidocaine 5% medicated plaster (Versatis®) reimbursement

Questions and Answers for Healthcare Professionals

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

Lidocaine 5% medicated plaster 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 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 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' general practitioner (GP) in relation to the indication for treatment. Approval will be granted for 3 months for treatment of patients with a diagnosis of PHN. If reimbursement is sought for an unlicensed indication this information can also be provided through the online application (Exceptional Circumstances).

When registered under PHN, approval is real-time and the patient will be approved for three months of reimbursement support.

Where the application is under Exceptional Circumstances, the application will be reviewed by the Medicines Management Programme (MMP) before a decision is made and communicated through the GP Application Suite to the GP. Approval status can also be checked by the pharmacy on the Pharmacy Application Suite (outlined in question 6).

5) How will prescribers submit this information?

This information can be submitted by the patients' GP through the **GP Application Suite under 'Special Drug Request'**.

6) How will GPs and Pharmacists review eligibility status?

Eligibility can be confirmed and monitored through the GP 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

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

Reimbursement approval will currently be granted for three months and if treatment is required to continue a further update of the application will be required.

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

The changes to reimbursement are effective for all newly initiated patients from 1 September 2017. For existing patients already on treatment the prescriber has 3 months in which to complete the application for continued reimbursement (for three months). After this time, no further reimbursement will be allowed 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 should I do if a recipient requires more than one box (containing 30 plasters) of lidocaine 5% medicated plaster (Versatis®)?

If patients have a requirement for more plasters due to particular circumstances (exceptional arrangements) their GP may submit this information on the online application to the PCRS stating the reasons for the extra allowance request.

11) 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.

Prescribing Tips and Tools for Lidocaine 5% Medicated Plaster (Versatis®)

Medicines Management Programme
Prescribing Tips and Tools

Lidocaine 5% medicated plaster is a local anaesthetic producing a local, non-systemic analgesic effect.
It is licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia [PHN]) in adults.

Prescribing Tips & Practice Points

- ✓ Apply the plaster to intact, dry, non-irritated skin (after healing of shingles)
- ✓ Each plaster must be worn for no longer than **12 hours**
- ✓ The minimum number of plasters that provide therapeutic relief should be used
- ✓ In total, not more than 3 plasters should be used at the same time
- ✓ The plaster should be cut to appropriate size with scissors **PRIOR** to removing the clear release liner
- ✓ Treatment outcome should be re-evaluated after **2 – 4 weeks**
- ✓ If no response is observed or if relieving effect is solely related to the protective properties of the plaster on the skin, **treatment SHOULD be discontinued**
- ✓ Treatment should be assessed at regular intervals to evaluate the need to continue treatment
- ✓ Use with caution in severe cardiac, renal and hepatic impairment

Information for Patients

- ✓ The plaster must be applied directly to the painful site as the mode of action is local and non-systemic
- ✓ When a pack (containing 5 plasters) has been opened, the plasters must be used within 14 days
- ✓ Always re-seal the pack to prevent the plasters from drying out

Criteria for the reimbursement of Lidocaine 5% Medicated Plaster

- ➢ Lidocaine 5% medicated plaster should **ONLY** be prescribed for the treatment of neuropathic pain associated with post-herpetic neuralgia (PHN) in adults
- ➢ In exceptional circumstances, there may be a need to prescribe lidocaine 5% medicated plaster for unlicensed indications

Treatment initiation

- All new patients commenced on lidocaine 5% plaster must be registered by their GP via the GP Application Suite prior to initiation of treatment
- The application will be approved if the indication of PHN is specified
- This will authorise reimbursement for a period of 3 months

Authorisation for unlicensed indications

- Reimbursement for unlicensed indications can also be applied for on the online system
- Information required to be submitted includes the patient's diagnosis, location of the pain as well as a history of past and current treatments
- The application will be reviewed by the Medicines Management Programme prior to a reimbursement approval decision

Additional information

- ❑ Reimbursement for an additional 3 months will require a further application
- ❑ Patients eligibility can be confirmed by accessing 'Eligibility Confirmation' on the GP and Pharmacy Application Suites through 'Online Services' on www.pcrs.ie

Product alternative and price comparison for the topical treatment of post-herpetic neuralgia (PHN)

Lidocaine 5% plaster (Versatis®)

Apply 1 to 3 plasters daily (12 hours on, 12 hours off)

Price
€77.52 (30) - €232.56 (90)

→ **Capsaicin 0.075% Cream**
(Axsain®) 45g

Apply sparingly 3 to 4 times daily

Price
€17.52 (45g)

Product alternatives and price comparisons of other topical treatments for non-post herpetic neuralgia (PHN) indications

Lidocaine 5% plaster (Versatis®)

UNLICENSED USE

Price
€77.52 (30)- €232.56 (90)

	Indication & dose	Price per 100g
→ **Diclofenac 1% gel** (e.g. Difene®) 50g*	Trauma of ligaments, tendons, muscles, joints & soft tissue rheumatism. ***Apply 2 to 4 times daily.***	**€2.36**
→ **Ibuprofen 5% gel** (e.g. Phorpain®) 100g *	Topical anti-inflammatory analgesic for back, rheumatic & muscular pain, strains & neuralgia. ***Apply sparingly up to 3 times daily.***	**€4.07**
→ **Ketoprofen 2.5% gel** (e.g. Fastum®) 100g	Local relief of pain and inflammation associated with muscular, rheumatic & soft tissue. ***Apply 2 to 3 times daily.***	**€6.69**

*Where more than one product is available the lowest cost product is listed.
Prices are correct as of 25 July 2017.

Version 1.2 MMP July 2017. Full evaluation available on www.hse.ie/yourmedicines. Contact mmp@hse.ie for more details.
References: SmPC Axsain®, Difene®, Fastum®, Phorpain® & Versatis® available at www.hpra.ie; PCRS online available at www.pcrs.ie

CLINICAL EVIDENCE DEMONSTRATING THE BENEFIT OF LIDOCAINE 5% MEDICATED PLASTER IN ALL TYPES OF PAIN OTHER THAN POST-HERPETIC NEURALGIA IS LIMITED

Please see overleaf for more information on alternative treatment options for post-herpetic neuralgia (PHN) and other types of pain

CLINICAL EVIDENCE DEMONSTRATING THE BENEFIT OF LIDOCAINE 5% MEDICATED PLASTER IN ALL TYPES OF PAIN OTHER THAN POST-HERPETIC NEURALGIA (PHN) IS LIMITED AND THEREFORE ITS USE FOR INDICATIONS SUCH AS MUSCULAR, JOINT OR SOFT TISSUE PAIN IS NOT RECOMMENDED

If Lidocaine 5% Medicated Plaster is prescribed it MUST be reviewed regularly and treatment SHOULD be discontinued if ineffective or if the relieving effect is solely related to the protective properties of the plaster. Licensed alternatives for both PHN and muscular type pain are outlined below

Example	Alternative topical treatment options for PHN indication **Capsaicin 0.075% cream** (Axsain®)	Alternative topical treatment options for non-PHN indications **Diclofenac 1% gel** (e.g. Difene®, Diclac®, Voltarol Emulgel®)
Indication	Symptomatic relief of neuralgia associated with & following PHN after the healing of lesions & painful diabetic peripheral polyneuropathy* *specialist prescribing only	Symptomatic relief of pain & inflammation in trauma of the ligaments, tendons, muscles, joints & localised forms of soft tissue rheumatism
Prescribing information	Apply to the affected area 3 to 4 times daily after the healing of herpes zoster infection	Apply to the affected area 2 to 4 times daily for up to 14 days Treatment duration for the above indications should not normally exceed 6 weeks
Cost	➢ €17.52 (45g tube)	➢ €1.18 – €1.80 (50g tube)
Patient information	• Apply a pea size amount • Wash hands immediately after application • Apply only to intact skin • Do not apply near the eyes	• The amount to be applied is dependant on the size of the area to be treated e.g. 2g to 4g (size of a cherry to the size of a walnut) is sufficient to treat an area of 400cm² to 800cm² • Applied only to intact skin • Wash hands after application
Special precautions	• A transient burning sensation can occur if: ➢ applied more than 4 times daily ➢ applied too often ➢ applied just before or after a hot shower • The vapour can cause brief irritation of the eyes, nose & throat • Skin irritation can occur e.g. stinging or itching	• Application over extensive areas or in excess of recommended dosage may give rise to systemic effects. Refer to the individual SmPCs for more information • To reduce undesirable effects use the minimum effective dose for the shortest possible duration • Use with caution in the elderly & treatment is contraindicated in patients <14 years • Discontinue if a rash develops after applying the gel

Appropriate management of pain

- ✓ If topical treatment does not provide sufficient pain control, consider the use of oral agents for the treatment of pain e.g. Paracetamol ± NSAIDs (see below)
- ✓ Patients should be counselled on the importance of maintaining a healthy lifestyle including exercise (e.g. walking or swimming) and weight loss to enhance strength and balance and help ease pain
- ✓ Use best practice guidelines to guide treatment choices for certain types of pain (e.g. NCEC Clinical Guideline for the Management of Cancer Pain in Adults)
- ✓ Always refer to the individual Summary of Product Characteristics (SmPCs) and other appropriate reference sources (e.g. British National Formulary [BNF]) to inform decisions with individual patients

First-line oral therapies for the treatment of pain

Paracetamol: 500mg to 1g every 4 to 6 hours
- ➢ Maximum 4g in 24 hours

NSAIDs e.g. ibuprofen: Initially 200 to 400 mg 3 to 4 times daily
- • Increase if necessary up to 600mg 4 times daily
- ➢ Aim for a maintenance dose of 200 to 400mg 3 times daily

± Adjuvant. Adjuvant analgesics are medicines that are not primarily designed to treat pain but can be used for this purpose
- ➢ Adjuvants that may be used in the treatment of neuropathic pain include: **gabapentin & amitriptyline** (unlicensed use)

References and Useful Resources

- **British National Formulary (BNF) July 2017.**
- **International Association for the Study of Pain (IASP).**
- **National Clinical Effectiveness Committee (NCEC)- Pharmacological Management of Cancer Pain in Adults.** Clinical Guideline No. 9- November 2015.
- **National Institute for Health and Care Excellence (NICE) Guidance CG173- Neuropathic pain in adults: Pharmacological management in non-specialist settings**. Updated February 2017.
- **Summary of Product Characteristics (SmPCs) Axsain®, Difene®, Diclac® & Voltarol Emulgel®**.
- **The Irish Pain Society.**
- **World Health Organisation (WHO) Pain Ladder for Adults.**

Version 1.2 MMP July 2017. Full evaluation on www.hse.ie/yourmedicines. Contact mmp@hse.ie for more details.