HSE PRIMARY CARE

REIMBURSEMENT SERVICE

REIMBURSABLE LIST OF

URINARY AND OSTOMY PRODUCTS

GUIDELINES FOR MANUFACTURERS/DISTRIBUTORS

1. INTRODUCTION

1.1. These guidelines have been prepared by the HSE National Expert Group for the information of Manufacturers/Distributors of Urinary and Ostomy Products. Additions to the Reimbursable List will be considered in compliance with the Health (Supply and Pricing of Medical Goods) Act, 2013.

1.2. There are two types of submission for products:

Type 1 - New Products

Type 2 - Existing Products

1.3. These guidelines are applicable to both Type 1 and Type 2 products.

1.4. Please note that samples of products and/or packaging for Type 1 applications **will** be requested by the HSE following initial review of the application.

1.5. Please note that samples of products and/or packaging for Type 2 applications **may** be requested by the HSE following initial review of the application.

1.6. Products used on the body, or inserted into the body, must not cause an adverse or toxic reaction.

1.7. Products must be suitable for self administration use under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use.

1.8. Products must be cost effective. It will be a matter for the National Expert Group to determine whether a product application is cost effective. The HSE reserves the right to request a mini Health Technology Assessment (HTA) on any product application received.

1.9. Applicants will be required to submit additional supporting documentation if requested to do so by the HSE in order to evaluate the cost effectiveness of a product. Examples of this additional documentation may include reports of reducing wastage; comparisons with similar products; value for money initiatives etc.

1.10. Products must not be advertised or promoted to the public in everyday magazines/newspapers/TV/radio. However marketing activity which is aimed primarily at healthcare professionals is acceptable. Claims for patient outcome improvement should be supported by clinical evidence. Online advertising can present difficulties where claims for patient outcome improvement are made without the clinical evidence to support the claim.

Advertising in journals which are aimed at healthcare professionals is acceptable. Advertising through social media campaigns or journals which have no relevance for healthcare professionals are not.

1.11. The list of Urinary and Ostomy products reimbursable under the GMS and Community Drugs Schemes will be maintained in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013.

Applicants should note that the interchangeability or substitution clause in the Act is intended for those medicinal products deemed interchangeable by the Health Products Regulatory Authority (HPRA) and it is not intended to be applied for medical devices.

1.12. The Classifications of Products listed may be subject to change from time to time.

1.13. The HSE operates a strict no price increase policy in relation to contract and reimbursement prices for goods and services. The reimbursement prices will remain in place unless otherwise agreed between the HSE and the Applicant.

1.14. The HSE intends to review the reimbursement pricing on an annual basis after go-live. The review will be based on the published pricing rules and will seek to ensure that the reimbursement prices continue to underpin the availability of quality products and services for eligible patients while delivering affordability and value for money for the Irish State. Applicants will be informed in advance of each pending review and may submit additional data to the HSE at the time for the review in order to provide supplementary evidence in relation to their pricing arrangements.

1.15. Application Fees will be applied in line with the Health (Reimbursement List) (Application Fees) Regulations 2016. When approval is granted, the relevant fee must be paid. A confirmation of payment and final artwork must be submitted to the HSE Primary Care Reimbursement Service (PCRS) prior to publication on the Reimbursement List.

1.16. All Urinary and Ostomy product application forms are to be submitted to:

reimbursement.applications@hse.ie

2. APPLICATION PROCESS – TYPE 1 (NEW PRODUCTS)

2.1. This process should be followed by Applicants when they wish to have a new product added to the list of Urinary and Ostomy products on the PCRS Reimbursement List.

2.2. Applicants should complete the Type 1 Application Form (Appendix 1) for each new product they wish to have included on the PCRS Reimbursement List. A signed copy of the Type 1 Application Form, along with appropriate backup material, should be sent electronically to the HSE at the email address on the Application Form.

2.3. (a) A single Application Form and supporting documents should be submitted to cover each new product.

(b) A single Application Form and supporting documents should be submitted for each size of a new product.

(c) Each Application Form and supporting documents should be submitted in a separate email.

(d) The HSE will issue an acknowledgement email containing a unique reference number for the application.

2.4. The HSE will conduct an initial review of the electronic application to ensure that all necessary documentation has been submitted. Once the required documentation is confirmed the HSE will request the Applicant to submit samples and packaging of the proposed new products.

2.5. Product samples should be identical to the final product, though not necessarily from a production run if this is impractical. The text of the proposed labelling / artwork should be final although it may be presented in mock up form if the finally produced version is not available.

2.6. As part of their Application Form, Applicants will be required to identity the appropriate Product Classification from the list at Appendix 3 for their product. Applicants should identify the appropriate Product Classification as those which offer an equivalent technical solution and/or an equivalent level of clinical care for patients.

2.7. In the event that the product requires a new classification, Applicants should identify this fact on the application form and submit their reasons for the new classification in the appropriate section.

2.8. Once all of the required documentation and product samples/packaging has been received by the HSE, the application will be assessed by the National Expert Group at its next scheduled review meeting.

2.9. The National Expert Group will assess each product application, including samples and supporting documentation from a clinical and technical perspective in the first instance. This will determine whether the evidence provided justifies the product being included on the Reimbursement List.

2.10. For those products which are approved by the National Expert Group, the reimbursement price will be agreed in accordance with the pricing rules in Section 10 of this document.

2.11. The HSE will aim to ensure that the reimbursement price of the new product is equivalent to products already listed in the appropriate product classification, having regard to difference in sizes etc. Where Applicants request a price premium for their new product, they are required to outline in their application the factors which they believe justify the premium.

2.12. The National Expert Group shall be authorised to make the final recommendation to the HSE for the inclusion or otherwise of products on the PCRS Reimbursement List.

2.13. Where Applicants are not satisfied with the decision of the National Expert Group on a product application, for example in relation to the inclusion or rejection of a product or the proposed reimbursement price, they may submit a representation to the HSE on the matter together with relevant additional information. The National Expert Group will assess the additional information provided with the representation at its next scheduled review meeting to determine whether the decision should be changed.

3. APPLICATION PROCESS – TYPE 2 (EXISTING PRODUCTS)

3.1. The application process for Type 2 should be followed by Applicants when they wish to notify the HSE of a discontinuation or minor change to an existing product on the list of Urinary & Ostomy Products on the HSE Reimbursement List.

3.2. Applicants should complete the Type 2 Application Form (Appendix 2) for each existing product when wishing to notify the HSE of a discontinuation or minor change. A signed copy of the Type 2 Application Form should be sent electronically to the HSE at the email address on the Application Form.

3.3. (a) A single Application Form and supporting documents should be submitted to cover each Type 2 Application

(b) Each Application Form and supporting documents should be submitted in a separate email.

(c) The HSE will issue an acknowledgement email containing a unique reference number for the application.

3.4. Examples of minor changes to existing products would be, product name change, a change in Manufacturer / Distributor of the product, a change in packaging (including product reference codes), a change in product specification.

3.5. The HSE will conduct an initial review of the electronic Type 2 Application Form to ensure that sufficient information has been provided. The HSE reserves the right to request additional documentation and/or product samples/packaging from the Applicant prior to consideration of the application.

3.6. Once all of the required documentation has been received by the HSE, the application will be assessed by the National Expert Group at its next scheduled review meeting.

3.7. The National Expert Group will assess each application, and determine whether the discontinuation/ minor change can be accepted by the HSE.

3.8. Products that are approved for discontinuation from the Reimbursement List shall remain live on the Reimbursement List for a period of at least 12 months to allow for patient transition to an alternative product if required.

4. MANDATORY CRITERIA FOR URINARY & OSTOMY PRODUCTS

4.1. In order to have an application accepted, Applicants must demonstrate that :-

4.1.1 The proposed product complies with the appropriate British Standard, ISO Standard or any other equivalent standard in force in a Member State of the European Union;
or

4.1.2 The proposed product complies with applicable national standards, incorporating EC Standards, including Medical Devices 2007/47/EC (as amended) with each product carrying the CE marking;.
and

4.1.3 The proposed product complies with the criteria set out in these guidelines;
and

4.1.4 For Type 1 Applications only, that the application demonstrates User acceptability by the presentation of the results of Clinical Trials which must have been conducted independently of the Manufacturer. Minimum data requirements for Clinical Trials are set out at Section 8 (Urinary) and Section 9 (Ostomy) of these guidelines.

5. SPECIFIC CRITERIA FOR URINARY PRODUCTS

5.1. Incontinence Sheaths/External Catheters

Incontinence Sheaths/External Catheters may be:

(a) one piece or two piece;

(b) adhesive or non adhesive

One Piece and Two Piece Systems

5.1.1. Sheaths must be manufactured from material that is non-abrasive to the skin, is impermeable to water but allows air to permeate.

5.1.2. Each sheath must have a universal connector to allow connection to a urinary drainage/leg bag.

5.1.3. Sheaths must be available in a variety of sizes: 18mm - 40mm, the minimum range must be 25mm - 35mm.

5.1.4. Adhesive/adhesive strips must not cause any skin reaction and/or breakdown.

5.1.5. One piece system – each sheath must have adequate adhesive to ensure it remains in place under normal circumstances for a minimum wear time of twelve hours.

5.1.6. Two piece system –must have adequate adhesive to ensure it remains in place under normal circumstances for a minimum wear time of twelve hours.

5.1.7. Each sheath must be easily removed, without causing skin trauma.

5.1.8. The adhesive must be easily removed, without causing skin trauma.

5.1.9. Sheaths must be individually wrapped and packed in boxes of 30 and in the case of a two piece system must contain an adhesive strip.

5.1.10. A measuring guide must be available for correct fitting and must be included in each box or made available to patients as required.

5.1.11. Each box of sheaths must be clearly marked to allow for easy identification.

5.1.12. Each box of sheaths must contain a leaflet with application directions – this must be easily understood by the client and include illustrations for ease of comprehension.

5.2. Leg Bags and Holders

5.2.1. Leg bags must be available in varying capacities, from 250ml to 1500ml.

5.2.2. Leg bags must be available;

(a) sterilised (for use with indwelling catheters); or
(b) unsterilised (for use with incontinence sheaths).

5.2.3. All sterilised bags must have a non-return valve at the top of the bag.

5.2.4. All sterilised bags must have a needle-free sampling port.

5.2.5. Leg bags must be available in packs of not greater than 10. Each pack must contain a minimum of 1 set of leg straps. Upon request, additional leg straps must be made available FOC.

5.2.6. Each box must contain a leaflet with instructions for use stating minimum wear time i.e. one week under normal circumstances.

5.2.7. When in contact with the skin, leg bags must not cause skin irritation.

5.2.8. Leg bags must be available in a variety of tubing lengths. The minimum length must be direct, i.e. connects directly to the sheath/catheter.

5.2.9. Leg bag and tubing must be sold as one unit.

5.2.10. Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routing.

5.2.11. Connectors on leg bag must be universal.

5.2.12. The tap must be easily opened and closed i.e. user-friendly and must not pose a hazard when left in an open position i.e. when the leg bag is used in conjunction with a night drainage bags

5.2.13. Straps must be elasticated and/or adjustable. The fastening must be sufficient to ensure that the leg bag is held in place when the bag is full. When in contact with the skin, the strap must not cause skin irritation. Straps must be included in the leg bag pack –1 set of straps per ten leg bags is acceptable, but additional leg straps must be made available free of charge (FOC), if requested.

5.2.14. A sleeve will be acceptable as an alternative to straps

5.2.14.1. Sleeves should be available in a variety of sizes (small, medium, large & extra large).

5.2.14.2. The sleeve should be machine washable or disposable

5.2.14.3. The sleeve should ensure that the leg bag is held in place when the bag is full.

5.2.14.4. The sleeve should not cause skin irritation when in contact with skin

5.2.14.5. The sleeve should last for a minimum of 1 week.

5.2.15. A smaller bag (250mls) may be required for intermittent urinary leaks or dribbling.

5.3. Urinary Catheters

5.3.1. Catheters may be:-

(a) indwelling catheters for short term use – minimum wear time of 7 days under normal circumstances.

(b) indwelling catheters for long term use suitable for urethral and suprapubic – maximum wear time of 12 weeks under normal circumstances.

(c) indwelling catheters for medium term use – wear time 4 weeks or as per manufacturer's instructions.

(d) intermittent self-catheterisation catheters –

- Nelaton – single use only.
- Hydrophilic or coated – single use only.
- Incorporating drainage bags.
- Compact/discreet.
- Catheters, Dilatation without Drainage Eyes.
- Catheters with Balloon Dilators.

5.3.2. Catheters must be composed of silicone, non silicone, latex coated or non coated: or other suitable material in the case of:

a) indwelling short term

b) indwelling long term

c) indwelling medium term

d) intermittent self catheterisation.

5.3.3. Catheters must be smooth and free from surface irregularities – they must appear clean and free from extraneous matter when examined by normal or corrected vision.

5.3.4. Indwelling catheters must be sterile, with the expiry date of sterility clearly marked on both the inner and outer packaging. It is recommended to come with two removable stickers, detailing size, batch expiry date etc.

5.3.5. Intermittent catheters must be sterile, with the expiry date of sterility clearly marked.

5.3.6. A recognised mark of sterilisation must be visible on each unit of packaging.

5.3.7. In the case of indwelling catheters each catheter must have a universal connector, to allow connection to a drainage system without the use of a separate connector.

5.3.8. Catheters must be available in female length (22cm. approximately) and standard length (40cm. approximately).

5.3.9. Intermittent female catheters available in a wide range of compact/discreet lengths (e.g. from 3.5cm to the normal size 20cm).

5.3.10. Intermittent male catheters should also be available in a wide range of compact/discreet sizes (e.g. from 10Ch to 18Ch), compact or standard.

5.3.11. Option of collecting bag attached with intermittent catheters to be available.

5.3.12. State if for single use or reusable.

5.3.13. Catheters should be available in a wide range of Charriére sizes (e.g. 10Ch. to 30Ch). And intermittent catheters should also be available in a wide range of Charriére sizes (e.g. 8Ch. to 18Ch).

5.3.14. Catheters for paediatric use should be available in a wide range of sizes (e.g. 6Ch. to 10Ch) – the length of paediatric catheters must be 25cm approximately.

5.3.15. Indwelling catheters should be available in a wide range of balloon sizes (e.g. ranging from 3ml (paed) to 30ml). The volume required to inflate the balloon must be clearly marked on the packaging. The standard balloon size is 10mls.

5.3.16. In the case of indwelling catheters, Charriére size and balloon size must be detailed on the packaging and on the universal connector of each catheter.

5.3.17. Indwelling and intermittent catheters may be available with varying tips, e.g. Round, Couvelaire, Dulour, Le Guillon, Nelaton and Tiemann tip.

5.3.18. Intermittent catheters may be self-lubricating e.g. with Polyvinylpyrrolidone (P.V.P.) hydrophilic coating or lubricant on the surface of the catheter. Any lubricant used must be sterile, non-toxic and certified as such by a recognised body.

5.3.19. In the case of:

a) indwelling catheters short term – pack sizes must not exceed 10.
b) indwelling catheters long term – individually wrapped sterilised within pack.
c) indwelling catheters medium term - must not exceed 5.
d) indwelling catheters can come as a complete kit.
e) intermittent catheters (i) Nelaton – pack sizes must not exceed 30-50
(ii) Lubricated – pack sizes must not exceed 30.

5.3.20. It is preferable that intermittent catheters would have universal colour coding for size purposes for the client and the Pharmacist for order purposes.

5.3.21. In the case of intermittent catheters, each box should contain a leaflet with instructions for use and care after use.

5.3.22. Outer packaging must be durable to avoid damage to products during transport and/or storage with easy to identify Charrière size, type of catheter and length.

5.3.23. Instructions for storage must be given to Pharmacist and client by the supplier, e.g. avoid kinking of catheter, avoid direct sunlight, avoid damp conditions, store flat, etc.,

5.4. Catheter Valves

5.4.1. The materials used in manufacturing valves must be smooth and free from surface irregularities.

5.4.2. Catheter valves must have a universal inlet connector. This connector should be non slip and secure.

5.4.3. Each catheter valve must have an outlet connector which is universal. This allows for the use of a drainage system either leg or overnight drainage bag.

5.4.4. Catheter valves must have an opening mechanism which is easy to use, i.e. user-friendly and minimising the risk of hand contamination.

5.4.5. The tap must have the facility to be left in an open or closed position. The tap must not pose a hazard when left in the open position, i.e. when used in conjunction with leg or overnight drainage bag.

5.4.6. All catheter valves must be sterile. A recognised mark of sterilisation and expiry date of same must be clearly marked on inner and outer packaging.

5.4.7. Each catheter valve must be individually wrapped sterilised.

5.4.8. Each box of catheter valves must contain a leaflet with directions for use, which must be easily understood by the client and include illustration for ease of comprehension. Instructions must state minimum wear time, i.e. 7 days under normal circumstances.

5.5. Overnight Drainage Bags

5.5.1. Drainage bags may be:-

a) drainable; or

b) non-drainage.

5.5.2. Drainable bags must be available:-

a) sterilised (for use with indwelling catheters); or,

b) unsterilised (for use with incontinence sheaths).

5.5.3. All sterilised bags must have a non-return valve at the top of the bag.

5.5.4. All sterilised bags must have a needle-free sampling port.

5.5.5. Sterilised bags must be available singly and unsterilised bags must be available in packs of 10 to 30.

5.5.6. Each box must contain a leaflet with instructions for use, stating minimum wear time under normal circumstances in the case of-

a. drainable – one week.

drainable bags for use with catheters should be sterile when used, and discarded when disconnected, max use for 7 days if on continuous drainage.

b. non-drainable – 12-24 hours.

non-drainable bags to be discarded when ¾ full (12-24 hrs).

5.5.7. The length of tubing must be 1,000mm approximately.

5.5.8. Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routeing.

5.5.9. Connectors must be universal.

5.5.10. In the case of drainage bags the tap must be easily opened and closed, i.e. user-friendly.

5.5.11. A smaller bag (250 mls) may be required for intermittent urinary leaks or dribbling 250 mls.

5.5.12. Bed/floor bag holder(s) should be provided FOC by the drainage bag supplier, as required by the client.

5.6. Retracted Penile Continence System

5.6.1. Plastic

5.6.1.1. Must be of good quality and be odour proof.

5.6.1.2. Must be flexible and comfortable.

5.6.1.3. Must be discreet and unobtrusive.

5.6.1.4. Must be quiet film.

5.6.2. Bag (with tap)

5.6.2.1. Bags must be available in boxes of not greater than 10.

5.6.2.2. Each box of bags must contain a leaflet with application directions – this must be easily understood by the client and include illustrations for ease of comprehension. Instructions must clearly state minimum wear time, i.e. 1-3 days under normal circumstances.

5.6.3. Adhesive

5.6.3.1. Must be easy to apply and remove.

5.6.3.2. Must be secure.

5.6.3.3. Must be comfortable.

5.6.3.4. Must incorporate a skin protective.

5.6.3.5. If the appliance incorporates an adhesive tape, the tape must be non-allergic.

5.6.4. Taps

5.6.4.1. The tap must be easily opened and closed, i.e. user-friendly and must not pose a hazard when left in an open position.

5.6.5. Connectors

5.6.5.1. Connectors on retracted penile continence system bags must be universal to facilitate easy attachment to night drainage and/or leg bags.

5.7. Nephrostomy Drainage

5.7.1. Nephrostomy bags must be available in a variety of capacities, from 350ml-500ml.

5.7.2. Nephrostomy bags must be sterile.

5.7.3. Nephrostomy bags must have a non-return valve at the top of the bag.

5.7.4. Should be available in packs not greater than 10.

5.7.5. Each box must contain a leaflet with instructions for use stating minimum wear time i.e. one week under normal circumstances.

5.7.6. When in contact with the skin, nephrostomy bags must not cause skin irritation.

5.7.7. Nephrostomy bags must be available in a variety of tubing lengths. The minimum length must be direct.

5.7.8. Nephrostomy bag and tubing must be sold as one unit.

5.7.9. Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routing.

5.7.10. The tap must be easily opened and closed.

5.7.11. There may be a requirement for a connector to connect nephrostomy bag to a night drainage bag.

5.7.12. Straps must be elasticated and/or adjustable. The fastening must be sufficient to ensure that the nephrostomy bag is held in place when the bag is full. When in contact with the skin, the strap must not cause skin irritation. Straps must be included in the nephrostomy bag pack.

5.8. Catheter Securement

5.8.1. Comfortable to wear to prevent traction / movement or pulling on the catheter.

5.8.2. Easy to apply and remove that doesn't cause skin damage.

5.8.3. Fits any size catheter.

5.8.4. Each box of devices must contain application directions – this must be easily understood by the client and include illustrations for ease of comprehension. Instructions must clearly state minimum wear time, i.e. 3-5 days under normal circumstances.

5.8.5. When in contact with the skin, they must not cause skin irritation.

5.8.6. May be single use or machine washable.

5.9. Spigots

5.9.1. Spigots should be sterile.

5.9.2. Spigots should be of durable plastic.

5.10. Urinary Clamps/Dribble Stops

5.10.1. Applies pressure to penis without skin damage.

5.10.2. Discreet and comfortable to wear.

5.10.3. Adjustable for the individual.

5.10.4. Available singly.

5.10.5. Each box of bags must contain a leaflet with application directions – this must be easily understood by the client and include illustrations for ease of comprehension. Instructions must clearly state minimum wear time, i.e. 24 hour bladder control under normal circumstances.

5.11. Catheter Maintenance Solutions (CMS)

5.11.1. The materials used in manufacturing of CMS must be compatible with the connectors.

5.11.2. Catheter solutions must have a universal inlet connector, suitable to attach to all catheters.

5.11.3. This connector should be non slip and secure.

5.11.4. CMS must have an opening mechanism which is easy to use, i.e. user-friendly and minimising the risk of hand contamination.

5.11.5. CMS must have the facility to be left in an open or closed position.

5.11.6. All CMS must be sterile. A recognised mark of sterilisation and expiry date of same must be clearly marked on inner and outer packaging.

5.11.7. Each CMS must be individually wrapped and available in boxes of 10.

5.11.8. Each box of CMS must contain a leaflet with directions for use, which must be easily understood by the client and include illustration for ease of comprehension. Instructions must state frequency of use.

5.11.9. Instruction on disposal of waste.

5.12. Trans Anal Irrigation

5.12.1. Pump/control unit /water holder and rectal catheters may be separate.

5.12.2. Supplies of rectal catheters must be available in boxes of not greater than 10-15.

5.12.3. Rectal Catheters must be smooth and free from surface irregularities – they must appear clean and free from extraneous matter when examined by normal or corrected vision.

5.12.4. Rectal catheters may be available in different sizes.

5.12.5. State if rectal catheters are for single use.

5.12.6. Rectal catheters may be self-lubricating or any lubricant used must be non-toxic and certified as such by a recognised body.

5.12.7. Pump system should be easily filled.

5.12.8. Each box must contain a leaflet with directions – this must be easily understood by the client and include illustrations for ease of comprehension. Instructions must clearly state how often this should be used.

5.12.9. Information on disposable of waste in every pack (i.e.: catheters do/do not flush down the toilet.

6. SPECIFIC CRITERIA FOR OSTOMY PRODUCTS

6.1. Ostomy Collection Pouches

6.1.1. Size (All Pouches)

6.1.1.1. All pouches except Fistula must be available in a wide range of gasket sizes.

6.1.1.2. Fistula pouches must be available as a standard "cut to fit".

6.1.2. Plastic (All Pouches)

6.1.2.1. The plastic must be of good quality and be odour proof.

6.1.2.2. Must be flexible and comfortable.

6.1.2.3. Must be discreet and unobtrusive.

6.1.2.4. Must be quiet film.

6.1.3. Pouch (All Pouches)

6.1.3.1. The pouch must have a soft, absorbent backing and be available in clear (including split cover variants) and opaque presentations.

6.1.3.2. Each box of pouches must be packed in box sizes ranging 10 – 30 units.

6.1.3.3. In the case of two piece systems, shelf containers and preferably unit and inner containers, must contain a statement as to which pouches and flanges will couple together.

6.1.3.4. Each box of pouches must contain a leaflet with application directions. Directions must be easily understood by the client and include illustrations for ease of comprehension.

6.1.3.5. A measuring guide must be available for correct fitting and must be included in each box or be available upon request. In the case of fistula pouches a template must be included.

6.1.4. Adhesive (All Pouches and Flanges)

6.1.4.1. Must be easy to apply and remove.

6.1.4.2. Must be secure.

6.1.4.3. Must be comfortable.

6.1.4.4. Must incorporate a skin protective.

6.1.4.5. If the appliance incorporates an adhesive tape, the tape must be non allergenic.

6.1.5. Filters

6.1.5.1. Filters must be discreet and effective.

(i.e. Odour or faecal material should not leak from the filter, they should prevent ballooning, designed to avoid blockage of the filter, waterproof in shower/bath or filter covers should be included in box of products).

6.1.6. Pouch Closures (Drainable, Fistula and Post-Op. Pouches)

6.1.6.1. Pouch closures should be integrated into the pouch.

6.1.6.2. Pouch closures should be easy to clean and allow for repeated opening and closing.

6.1.6.3. If a soft wire tie is the method of closure a minimum of one tie per pouch must be included

6.1.6.4. If a bung type closure is the method of closure the bung should be securely attached to the pouch.

6.1.6.5. Standard clip – 1 clip per ten pouches is acceptable.

6.1.7. Convexity

6.1.7.1. Convex products should identify the degree of convexity e.g. shallow or deep or more preferably the depth of convexity in mm's. This should be displayed on outer box.

6.1.7.2. Literature included with the pouch should outline appropriate use of and precautions required when using convexity. E.g. should be used under the supervision of a medical heathcare professional such as a stoma clinical nurse.

6.1.8. Taps (Urostomy)

6.1.8.1. The tap must be easily opened and closed i.e. user-friendly and must not pose a hazard when left in an open position i.e. when the pouch is used in conjunction with leg and night drainage bag.

6.1.9. Non-Return Valve (Urostomy)

6.1.9.1. Urostomy pouches must have a non-return valve.

6.1.10. Connectors (Urostomy)

6.1.10.1. Connectors on urostomy pouches must be universal to facilitate easy attachment to leg and night drainage pouches.

6.1.10.2. One connector per pack of 10 pouches is acceptable.

6.1.11. (Urostomy Drain Tubing)

6.1.11.1. Tubing must be constructed in material with anti kink properties, yet must be sufficiently flexible to allow easy manipulation and routeing.

6.1.12. Drainage Bags

6.1.12.1. Faecal ostomy pouch free drainage bags must;

6.1.12.1.1. Contain an instruction leaflet.

6.1.12.1.2. Have a capacity between 2 and 3 litres.

6.1.12.1.3. Be made from a good quality plastic.

6.1.12.1.4. Have volume measuring markings on bag.

6.1.12.1.5. Have a durable and secure emptying tap/device.

6.1.12.1.6. Have universal eyelets to attach bag to a stand.

6.1.12.1.7. Be available in pack sizes between 10-30 units.

6.1.12.2. Drainage bags for use with urostomy pouches - see "Criteria for Urinary Incontinence Products".

6.1.13. Flanges

6.1.13.1. Two Piece pouches must be easy to attach to flanges.

6.1.13.2. In the case of two piece systems, shelf containers and preferably unit and inner containers, must contain a statement as to which pouches and flanges will couple together within a range.

6.1.13.3. However there may be instances whereby a client may not achieve the minimum wear time. Consequently, users should be advised that the minimum wear time is conditional e.g. on there being no leakage from under the flange or an adverse skin reaction occurring.

6.2. Adhesive Removers

6.2.1. Must include clear Client instructions i.e.- wash skin following use.

6.2.2. Must not damage skin.

6.2.3. Must not cause pain on application.

6.2.4. Contents must be clearly marked.

6.2.5. Must be easy to use.

6.2.6. Must not compromise the adhesion of the new pouch being applied.

6.3. Belts

6.3.1. Must include clear Client instructions.

6.3.2. Must be comfortable next to skin i.e. plastic tabs.

6.3.3. Must be of washable fabric.

6.3.4. Must be compatible with pouches.

6.3.5. Must be easy to adjust.

6.4. Deodorants/Air Freshener

6.4.1. Must include clear Client instructions i.e. if applicable not to be sprayed on or near stoma.

6.4.2. Must be ozone friendly.

6.5. Irrigation/Plug Devices

6.5.1. Irrigation/Plug Appliances

6.5.1.1. Appliances must contain clear instructions with illustrations for client use.

6.5.1.2. Appliances must clearly state approximate length of time for which it can be used i.e. Pouch, Tubing, Cone - not less than 1 year.

6.5.1.3. Sleeves must be packed in boxes of 10-50 units.

6.5.1.4. Cones must be packed singly.

6.5.2. Irrigation Pouch

6.5.2.1. Plastic must be of good quality.

6.5.2.2. Capacity must be 1000mls. to 2000mls.

6.5.2.3. Volume capacity must be clearly labelled and easily read.

6.5.2.4. Pouch must incorporate a good quality holder/handle.

6.5.3. Irrigation Tubing

6.5.3.1. Must be of good quality plastic.

6.5.3.2. Must have anti-kink properties.

6.5.3.3. Must be flexible and easy to use.

6.5.3.4. Must incorporate a water controlling device which is easy to use.

6.5.4. Cone/Catheter

6.5.4.1. Material must be of good quality.

6.5.4.2. Must be soft.

6.5.4.3. Tip must be rounded for comfortable insertion and removal, without causing damage to the stoma or rectum.

6.5.4.4. Must be easy to remove from the tubing for easy cleaning.

6.5.5. Sleeves (One Piece)

6.5.5.1. Plastic material must be of good quality.

6.5.5.2. Adhesive must be easy to apply and remove from skin.

6.5.5.3. Sleeves must contain security clip i.e. for when the client wishes to walk around during the procedure.

6.5.5.4. Instructions must state length of time each sleeve can be used for i.e. single use.

6.5.6. Sleeves (Two Piece)

6.5.6.1. Plastic material must be of good quality.

6.5.6.2. Sleeve must be easy to apply to and remove from belt flange.

6.5.6.3. Sleeves must contain security clip i.e. for when the client wishes to walk around during the procedure.

6.5.6.4. Instructions must state length of time each sleeve can be used for i.e. single use.

6.5.6.5. Must state approximate length of time each belt can be used for i.e. minimum of 6 months.

6.5.7. Plugs (One Piece)

6.5.7.1. Material must be of good quality.

6.5.7.2. Material must be soft and comfortable.

6.5.7.3. Must be discreet and unobtrusive.

6.5.7.4. Must be easy to insert and remove without traumatising the stoma or peristomal skin.

6.5.7.5. Must incorporate an effective filter.

6.5.7.6. Must be available in a selection of sizes.

6.5.7.7. Must contain clear instructions and illustrations for use and disposal.

6.5.7.8. Must be packed in boxes of 10-30 units.

6.5.7.9. Adhesive must be secure, easy to apply and remove from skin.

6.5.7.10. Adhesive must incorporate a skin protective.

6.5.8. Plugs (Two Piece)

6.5.8.1. Base plate must be soft and comfortable.

6.5.8.2. Must be discreet and unobtrusive.

6.5.8.3. Adhesive must be secure, easy to apply and remove from skin.

6.5.8.4. Adhesive must incorporate a skin protective.

6.5.8.5. Must incorporate an effective filter.

6.5.8.6. Plug must be easy to attach and remove from base plate.

6.5.8.7. Must be packed in boxes of 10-30 units.

6.5.8.8. Must contain clear instructions and illustrations for use and disposal.

6.5.8.9. Must be available in a selection of sizes.

6.5.8.10. Plug must be easy to insert and remove without traumatising the stoma or peristomal skin.

6.6. Skin Fillers and Protectives (Sprays, Powders, Pastes and Wipes)

6.6.1. Contents must be clearly labelled.

6.6.2. Instructions must be clearly stated.

6.6.3. Must be easy to apply to and remove from skin.

6.6.4. Must not cause pain on application.

6.6.5. Must not cause damage to skin.

6.7. Skin Protectors (Seals/Rings)

6.7.1. Must adhere to moist skin.

6.7.2. Must be comfortable on skin.

6.7.3. Must be flexible on skin.

6.7.4. Must be available in a variety of sizes i.e. rings.

6.7.5. Must be easy to apply to and remove from skin.

6.7.6. Must contain Instructions.

6.8. High Output Pouches

6.8.1. Must have a bung type closure to allow for connection to free drainage if required.

6.8.2. Must have an adhesive resistant to corrosive effluent.

6.8.3. Convex high output pouches must have an option of attaching a belt.

6.8.4. Must have a larger than average pouch capacity.

6.9. Anal Plugs

6.9.1. Contents must be clearly labelled.

6.9.2. Instructions must be clearly stated.

6.9.3. Must be available in a variety of sizes.

6.9.4. Must be easy to apply to and remove from skin.

6.9.5. Must be individually wrapped.

7. GUIDELINES FOR CLINICAL TRIALS OF URINARY & OSTOMY PRODUCTS

7.1 This is applicable to Type 1 – New Products only.

7.2 An Applicant is required to submit the final report on a minimum of **two** Clinical Trials for each product being submitted as a Type 1 application.

7.3 It is not a prerequisite that the Clinical Trial must have been conducted in Ireland.

7.4 A Clinical Trial should ideally have been conducted by an appropriately qualified medical or nursing person who had no direct or indirect association with the manufacturer or proposed Irish distributor of the product. If there was any link between the manufacturer or proposed Irish distributor and the person who conducted the trial, this link should be declared on the Type 1 Application Form.

7.5 Each Clinical Trial must have been conducted at not less than 3 centres, with a minimum of at least 20 participants in total across the 3 centres.

7.6 Each participant in the Clinical Trial must have been fully informed of the trial procedures and his/her written consent must have been obtained.

7.7 Each product on trial must have been assessed on its own merit and without the benefit of any additional product, irrespective of whether the additional product is on the approved HSE reimbursable list of products.

7.8 A trial participant may have been withdrawn from the Clinical Trial at any time at the discretion of the person who conducted the trial.

7.9 The final report shall have set out at a minimum the length of the Clinical Trial, the patient cohort, the number of products used, the clinical outcomes achieved and any other relevant information.

7.10 Each manufacturer/distributor who initiated a Clinical Trial must have appointed a person who would have been responsible for co-ordinating each trial. The duties of a Co-ordinator should have included:-

- Preparing information booklets containing correct trial procedures,
- Formulating a questionnaire,
- Distributing the above documentation,
- Collecting the questionnaires,
- Collating the data,
- Presenting the results.

7.11 The manufacturer/distributor had responsibility for the supply of all products used for the trial including the necessary items that allowed a product to have been used effectively e.g. set of straps to have been used with leg bags.

7.12 Permission to carry out the trial must have been obtained by the Co-ordinator conducting the trial from the relevant authority.

7.13 The minimum requirements of the HSE which must have been provided for in the design and organisation of such trials are set out under “Minimum Dataset” of this document.

7.14 A manufacturer/distributor initiating a Clinical Trial must have supplied:-

- All technical details about its products including specifications and recommended wear time.
- Adverse reaction forms to the Co-ordinator who should have transmitted them to the person who conducted the trial.

7.15 The following were prerequisites for participation in a Clinical Trial:-

- Participants must have been willing to use the product on trial.
- Participants must have provided informed consent.
- Participants must have been able to comprehend and complete the questionnaire provided.
- Participants must have been established for the period outlined in the table below on the type of product under trial.

7.16 Exclusions:-

- Participants who were found to have had a skin assessment rating of 2, 3, or 4 must have be cleared by medical advice if they were included in the Clinical Trial:-

  0 = Normal intact skin,
  1 = Patchy redness,
  2 = Extensive redness,
  3 = Reddened blistered but not broken,
  4 = reddened with open areas of skin.

- Participants who were undergoing Radiotherapy or Chemotherapy treatment must also have been excluded from the trial.
- Products excluded from Clinical Trials are Post-op and Fistula pouches (Ostomy Products).

7.17 The following must have been compiled with when conducting a Clinical Trial:-

- Length of Trial – The minimum length of trial period must have been set for each specific product as indicated hereunder-

  - <u>Urinary Products:</u>

Classification	Period
Incontinence Sheath/External Catheters	7 Days
Leg Bags & Overnight Drainage Bags	7 Days
Straps/Sleeves	28 Days
Urinary Catheters	
(a) Indwelling Long Term	3 Months
(b) Intermittent Self Catheterisation	7 Days
(c) Indwelling Short/Medium Term	1 Month
Catheter Valves	14 Days
Retracted Penile Continence System	14 Days
Nephrostomy Drainage	7 days
Catheter Securement	7 days
Spigots	7 days
Urinary Clamps/Dribble Stops	7 days

Catheter maintenance solutions	7 days
Trans Anal Irrigation.	14 days

- Ostomy Products:

Classification	Period
One/Two Piece Closed Pouches	10-12 Days
One/Two Piece Open Pouches	18-20 Days
Urostomy Pouches	18-20 Days
Adhesive Remover	To be determined by the type of pouch being worn
Pouch Closures ·.	18-20 Days
Belts	To be determined by the type of pouch being worn
Deodorant/ Air Freshener	To be determined by the type of pouch being worn
Filters	10-12 Days
Irrigation /Plug Appliances(Pouch/Tubing/Cone/Sleeve)	28 Days
Skin Fillers & Protectives	To be determined by the type of pouch being worn
Skin Protectors	To be determined by the type of pouch being worn
Anal Plugs	28 days

- The minimum wear time for Pouches/Flanges under trial will have been the participants normal wear time for this type of product.

8 TRIAL MINIMUM DATASET – URINARY PRODUCTS

A questionnaire for each product on trial must have been provided by the Co-ordinator to the person who conducted the trial and this must have been completed by the trial participant.

8.1 Incontinence Sheath

8.1.1 Security.
8.1.2 Comfort.
8.1.3 Ease of application.
8.1.4 Ease of removal.
8.1.5 Adhesive residue.
8.1.6 Frequency of change – durability.
8.1.7 Wear time/Reasons for change.

8.2 Leg Bags & Overnight Drainage Bags

8.2.1 Sterilised.
8.2.2 Unsterilised.
8.2.3 Effectiveness of non-return valve.
8.2.4 Effectiveness of needle-free sampling port.
8.2.5 Ease of use of needle-free sampling port.
8.2.6 Effectiveness of tap.
8.2.7 Ease of opening of tap.
8.2.8 Tubing anti-kink properties.
8.2.9 Flexibility of tubing.
8.2.10 Ease of attachment to Night Drainage/Leg Bag.
8.2.11 Ease of removal from Night Drainage/Leg Bag.

8.3 Straps/Sleeves

8.3.1 Clear instructions.
8.3.2 Ease of application.
8.3.3 Comfort.
8.3.4 Effectiveness.
8.3.5 Skin health.

8.4 Urinary Catheters

8.4.1 Sterility mark.
8.4.2 Universal connector.
8.4.3 Balloon size.
8.4.4 Non-toxic.
8.4.5 Ease of opening
8.4.6 Ease of insertion
8.4.7 Ease of removal
8.4.8 Lubrication
8.4.9 Ease of handling

8.5 Catheter Valves

8.5.1 Connectors – Ease of attachment.
8.5.2 Connectors – Ease of removal.
8.5.3 Ease of opening of tap.
8.5.4 Ease of closing of tap.
8.5.5 Clear instructions.

8.6 Retracted Penile Continence System

8.6.1 Security.
8.6.2 Comfort.
8.6.3 Odour proof material.
8.6.4 Discreet.
8.6.5 Unobtrusive.
8.6.6 Noise/rustle factor.
8.6.7 Ease of application.
8.6.8 Ease of removal.
8.6.9 Adhesive effectiveness.
8.6.10 Skin health.
8.6.11 Effectiveness of tap.
8.6.12 Ease of opening of tap.
8.6.13 Ease of closing of tap.
8.6.14 Connectors – ease of attachment.

8.7 Nephrostomy Drainage

8.7.1 Sterilised.
8.7.2 Unsterilised.
8.7.3 Effectiveness of non-return valve.
8.7.4 Effectiveness of needle-free sampling port.
8.7.5 Effectiveness of tap.
8.7.6 Ease of opening of tap.
8.7.7 Tubing anti-kink properties.
8.7.8 Flexibility of tubing.

8.8 Catheter Securement

8.8.1 Clear instructions.
8.8.2 Ease of application.
8.8.3 Comfort.
8.8.4 Effectiveness.
8.8.5 Skin health.

8.9 Spigots

8.9.1 Sterilised.
8.9.2 Durability.

9 TRIAL MINIMUM DATASET – OSTOMY

A questionnaire for each product on trial must have been provided by the Co-ordinator to the person who conducted the trial and this must have been completed by the trial participant.

9.1 Pouches: One Piece Closed/Open

9.1.1 Security.

9.1.2 Comfort.

9.1.3 Odour proof material.

9.1.4 Noise/Rustle factor.

9.1.5 Aesthetic appearance.

9.1.6 Filter performance.

9.1.7 Ease of application.

9.1.8 Ease of removal.

9.1.9 Adhesive residue.

9.1.10 Backing paper - ease of removal.

9.1.11 Flexibility.

9.1.12 Capacity adequacy.

9.1.13 Frequency of change - durability.

9.1.14 Visibility/Profile.

9.1.15 Assessment of backing material -Comfort,
-Ability to absorb perspiration.

9.1.16 Wear time/Reasons for change.

9.1.17 Daily activities - Showering/bathing- Ease of drying,
-Filter performance,
-Adhesive performance.

9.1.18 Status of peristomal skin at final assessment.

9.2 Pouches: Two Piece System

In addition to points referred to under 8.1 above, the following must have been included in the Questionnaire-

9.2.1 Ease of attachment of flange to pouch.

9.2.2 Ease of removal of flange from pouch.

9.2.3 Incidence of "pop-off' occurrence.

9.2.4 Flanges - Flexible,
- Inflexible.

9.3 Urostomy Pouches

In addition to points referred to under 8.1 above, the following must have been included in the questionnaire-

9.3.1 Effectiveness of non-reflux valve.

9.3.2 Effectiveness or tap, security.

9.3.3 Ease of opening.

9.3.4 Ease of closing.

9.3.5 Ease of attachment to Night Drainage Bag/Leg Bag.

9.3.6 Ease of removal from Night Drainage Bag/Leg Bag.

9.3.7 Connectors - Ease of attachment,

- Ease of removal,

- Security.

9.4 Adhesive Removers

9.4.1 Clear instructions.

9.4.2 Damage to skin.

9.4.3 Pain on application.

9.4.4 Ease of application.

9.4.5 Compromising pouch adhesion.

9.5 Pouch Closures

9.5.1 Ease of application.

9.5.2 Ease of opening.

9.5.3 Ease of removal.

9.5.4 Security.

9.5.5 Ease of cleaning.

9.5.6 Comfort.

9.5.7 Discreet.

9.6 Belts

9.6.1 Clear instructions.

9.6.2 Ease of application.

9.6.3 Ease of removal.

9.6.4 Ease of belt adjustment.

9.6.5 Discreet.

9.6.6 Comfort.

9.6.7 Washable.

9.7 Deodorants/Air Fresheners

9.7.1 Clear instructions.

9.7.2 Effectiveness.

9.7.3 Ease of Usage.

9.7.4 Acceptability of perfume.

9.8 Filters

9.8.1 Visibility profile.

9.8.2 Effectiveness.

9.8.3 Acceptable wear time.

9.8.4 Leakage through filter.

9.9 Irrigation/Plug Appliances

9.9.1 Clear instructions.

9.9.2 Ease of storage/carriage.

9.10 Irrigation Bag

9.10.1 Plastic - Durability.

9.10.2 Capacity.

9.10.3 Labelling.

9.10.4 Holder - quality,

- effectiveness.

9.11 Irrigation Tubing

9.11.1 Anti-kinking.

9.11.2 Ease of handling.

9.11.3 Flexibility.

9.11.4 Water controlling device - ease of usage,

- effectiveness.

9.11.5 Ease of removal from cone.

9.12 Cone/Catheter

9.12.1 Ease of insertion/removal.

9.12.2 Comfortable.

9.12.3 Ease of removal from tubing.

9.12.4 Ease of cleaning.

9.13 Sleeves

9.13.1	Ease of application.	(1-Piece)
9.13.2	Ease of removal.	(1-Piece)
9.13.3	Comfortable.	(1-Piece)
9.13.4	Ease of usage.	(Security clip)
9.13.5	Effectiveness.	(Security clip)
9.13.6	Ease of application of flange to belt.	(2-Piece)
9.13.7	Ease of removal of flange from belt.	(2-Piece)
9.13.8	Comfortable.	(2-Piece)

9.14 Skin Fillers & Protectives (Sprays Powders Pastes & Wipes)

9.14.1	Clear instructions
9.14.2	Ease of application
9.14.3	Adherence to moist skin
9.14.4	Ease of removal where appropriate
9.14.5	Effectiveness

9.15 Skin Protectives (Seals/Rings)

9.15.1	Clear instructions
9.15.2	Ease of application
9.15.3	Adherence to moist skin
9.15.4	Ease of removal
9.15.5	Effectiveness

10. PRICING RULES HSE WILL APPLY TO ALL APPLICATIONS

10.1. In the first instance, each Type 1 product application will be assessed from a clinical and technical perspective to determine whether the evidence provided justifies the product being included on the Reimbursement List.

10.2. For Type 1 products which are approved and for all Type 2 products, the reimbursement price will be equivalent to the reimbursement price for the relevant product classification, having regard to differences to sizes etc.

10.3. The reimbursement price for each product classification will be determined on the basis of whichever is the lowest of;

10.3.1. UK adjusted price (at 12 month average exchange rate), or

10.3.2. Average of the lowest three European countries submitted, or

10.3.3. Price proposed to the HSE.

for the lowest price agreed for any product included in the relevant classification, having regard to differences to sizes etc.

10.4. The UK adjusted price will be based on the average rate of exchange over 12 months up to date of application, having regard to the prices quoted in the following;

10.4.1. C&D (the most current edition available at the time of pricing)

10.4.2. BNF (the most current edition available), if C&D unavailable

10.4.3. Submitted UK Price, if C&D and BNF not available

10.5. It will be a matter for the Applicant to supply sufficient supporting evidence to justify a premium above the proposed reimbursement price for the product classification.

10.6. In the event that a product requires a new classification, the reimbursement price will be determined using the same criteria as outline above. The HSE shall in all cases have the final say in relation to the inclusion or otherwise of a premium for new/innovative products.

10.7. The new Reimbursement List will be made available to patients, clinicians and suppliers via the PCRS section of the HSE website.

10.8. The HSE reserves the right to offer a reimbursement price which will be benchmarked against the prices(s) available to the HSE, for products that, in the opinion of the HSE National Expert Group, offer an equivalent technical solution and/or an equivalent level of clinical care for patients.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX 1

TYPE 1 - NEW PRODUCT APPLICATION FORM

New Urinary & Ostomy Products to be added to HSE Reimbursement List

1. General Information

Applicant Company Name:	
Product Name:	
Product Description:	
Product Pack Size:	
Product Reference Code:	
Product Specification:	
Manufacturer:	
Distributor to HSE Customers:	
Launch Date for Product in Ireland:	
Identify appropriate product classification (ref: Appendix 3)	
If no product classification is suitable, please provide justification for creation of a new classification:	
GMS Code of nearest comparator product:	
Proposed method of distribution for making the product available to HSE contractors (i.e GPs or Pharmacists)	
Previous use of the product in hospital or community areas in Ireland. Provide details of location, duration of use and average annual usage.	

2. Clinical Trials [1]

Summary Details of Clinical Trial No. 1:	
Summary Details of Clinical Trial No. 2:	
CE Certificate Submitted[2]:	
Please provide details of any link between the manufacturer or proposed Irish distributor and the person who conducted the trial	

3. Product Samples

See Section 2.5 and 2.6 of this Guidelines document for information of submission of product samples.

4. Proposed Prices

Reimbursement Price Proposed to HSE	€

United Kingdom Equivalent	
C&D (the most current edition available at time of application)	£
BNF (if C&D price is not available) (the most current edition available at time of application)	£

European Pricing			
United Kingdom	£	Country	€

[1] Please refer to Section 7 of this document for Guidelines for Clinical Trials of Urinary & Ostomy Products and Sections 8 & 9 Trial Minimum Datasets

[2] An electronic copy of a valid CE certificate for the product must be submitted with the application.

Country	**€**	Country	€
Country	€	Country	€
Country	€	Country	€
Country	€	Country	€
Average of the three lowest European Countries			
Country	Country	Country	Country
€	€	€	€

- United Kingdom price should be quoted in Pound Sterling.
- State the European Country and Reimbursement Price in Euro where this product is marketed and reimbursed under the country's Schemes/Insurance System.
- HSE will require independent validation of the European prices submitted which must accompany this form. Where this information is not available, please provide explanatory footnote/s in the table provided below.
- If this product is not available, specify N.A.

Reason for Price Submitted:

Name and Address of Key Contact for Application:

Name:

Position:

Address:

I confirm that the information provided in this application is correct.

Signature: _____ **Date:** _____

Telephone No: _____ **E-mail:** _____

The completed form along with application information should be submitted to:

reimbursement.applications@hse.ie

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX 2

TYPE 2 - EXISTING PRODUCT NOTIFICATION FORM

Existing Urinary & Ostomy Products on the HSE List of Reimbursable Items.

This form has been prepared to enable manufacturers/distributors to inform the HSE of any of the following in relation to existing Urinary & Ostomy Products on the HSE List of Reimbursable Items.

a) Intention to Discontinue Urinary Incontinence/Ostomy Products on the HSE Reimbursement List

b) Minor Changes of Urinary Incontinence/Ostomy Products on the HSE Reimbursement List

Note: This form must be completed for each product / GMS code on the existing HSE Reimbursement List irrespective of whether the notification concerns a discontinuation or minor change.

1. Product Details

GMS Code:	
Manufacturer:	
Distributor to HSE Customers:	
Product Name:	
Product Description:	
Product Pack Size:	
Product Reference Code:	
Product Classification: **(See Appendix 3)**	

2. Notification

(a) Intention to Discontinue Urinary or Ostomy Products on the HSE Reimbursement List

Applicants should complete this section if they wish to notify the HSE of their intention to discontinue the listing of a Urinary or Ostomy Product on the HSE Reimbursement List.

In the interest of maintaining an uninterrupted supply of Urinary & Ostomy products to patients, it is a requirement that products that are approved for discontinuation from the Reimbursement List shall remain live on the Reimbursement List for a period of at least 12 months to allow for patient transition to an alternative product if required

Proposed date for product discontinuation:	
Date (month and year) when it is estimated that stocks of product will be depleted:	
Where the product discontinuation is of a particular pack size within a range of products provide details of those products that will continue to remain available:	
Give reasons for the proposed product discontinuation of the product (s) with appropriate substantiating information:	
If there is a reimbursed alternative to the product being discontinued please provide details:	
Provide an evaluation of likely impact that the proposed discontinuation will have on the quality of patient care, including an estimate of the number of patients it will affect:	
Provide details of the current status and availability of the product in the various Member States of the European Union:	
A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the discontinuation of the product.	

(b) Minor Changes of Urinary or Ostomy Products on the HSE Reimbursement List

Applicants should complete this section if they wish to notify the HSE of a proposed Minor Change to a Urinary or Ostomy Product on the HSE Reimbursement List.

Changes to the product can include, for example:
Packaging of product (including pack size); Product Specification; Name of product; Manufacturer /Distributor of the product; Product Reference Code;

Details of Proposed Minor Change:	
Proposed date for Minor Change:	
Date (month and year) when it is estimated that stocks of currently listed product will be depleted:	
A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the minor change of the product:	

NOTE:

For ALL Minor Change notifications, an copy of the outer packaging artwork, CE certification, product samples and/or patient information leaflet for currently listed product AND proposed minor change product may be requested by the HSE following receipt of the electronic application.

Name and Address of Key Contact for Application:

Name:

Position:

Address:

I confirm that the information provided in this application is correct.

Signature: _____ **Date:** _____

Telephone No: _____ **E-mail:** _____

The completed form along with information should be submitted to:

reimbursement.applications@hse.ie

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX 3

PRODUCT CLASSIFICATIONS

URINARY
Catheter Maintenance Solutions
Catheter Securement
Catheter Valves
Catheters Non Silicone - Indwelling (Long Term)
Catheters Non Silicone - Indwelling (Medium Term)
Catheters Non Silicone - Indwelling (Short Term)
Catheters Non Silicone - Isc (Lubricated)
Catheters Non Silicone - Isc (Lubricated) Incorporating Drainage Bag
Catheters Non Silicone - Isc (Nelaton)
Catheters Silicone - Indwelling (Long Term)
Catheters Silicone - Isc (Lubricated)
Dilatation Catheters
Drainage Bags
Incontinence Sheaths
Intermittent Catheter Lubricated - Gms
Leg Bag Holder
Leg Bags
Nephrostomy Drainage
Retracted Penile Continence System
Trans Anal Irrigation
Spigots
Urinary Clamps/Dribble Stops

OSTOMY
Absorbents
Adhesive Hydrocolloid Barrier Extension
Adhesive Removers
Bag Closures
Belts
Colostomy Bags
Deodorants/Air Fresheners
Filters
Fistula Bags
High Output Pouches
Ileostomy (Drainable) Bags
Irrigation/Plug Appliances
Post-Op. Bags
Skin Fillers & Protectives (Barrier)
Skin Protectors (Wafers, Washers)
Stoma Caps
Tubing
Two Piece Ostomy Systems
Urostomy Bags