NICE advice

InterDry for intertrigo

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is InterDry. It is used for treating intertrigo, a common inflammatory skin rash that usually develops in skin folds, such as in the groin, under the breast or in the armpits.
- The **innovative aspects** are that the technology is designed to target all 3 factors associated with intertrigo: moisture, bacteria or fungi and friction from skin-to-skin contact.
- The intended **place in therapy** would be as an alternative to other treatment options used in managing intertrigo. This may include topical or systemic antimicrobial agents and corticosteroids, and absorptive materials such as gauze.
- The **main points from the evidence** summarised in this briefing are from 1 prospective single-arm observational study, 2 case series and 2 case reports including a total of 28 adults with intertrigo or complications associated with skin folds. Evidence suggests that InterDry may help to reduce the symptoms of intertrigo, including itching or burning, loss of skin layers, secondary lesions, redness and odour.

- **Key uncertainties** around the technology are that the available evidence is very limited in quantity and quality. Well-designed comparative studies would be helpful to determine the benefits over current management options. The care pathway for intertrigo in the UK is not well defined and standard care may vary.
- The **cost** of InterDry is £43.07 for the 25 cm × 91 cm pouch and £105.95 for the 25 cm × 366 cm roll (exclusive of VAT). The **resource impact** would be an initial cost increase compared with existing treatment options. This may be offset if the use of InterDry reduces overall treatment time and associated costs. There is no published evidence to support these claims.

The technology

InterDry (Coloplast Limited) for treating intertrigo is made of a non-sterile, polyester fabric that wicks away moisture from the skin and allows it to evaporate. It has a polyurethane coating that is designed to reduce skin-to-skin friction and silver within the fabric to provide antibacterial action. The company states the silver can also fight fungi, although evidence to support this is uncertain. According to the instructions for use, each piece of InterDry fabric can be applied for up to 5 days depending on soiling, odour, amount of moisture and general skin condition. It should be removed before bathing. The technology is available in the form of a non-sterile roll (25 cm × 366 cm) or pouch (25 cm × 91 cm). InterDry can be cut to size with clean scissors to cover the affected area. It should be secured to the skin in 1 of several ways: with the skin fold, with skin-friendly tape, or by tucking under clothing.

Innovations

InterDry is designed to target the 3 main factors associated with intertrigo: moisture from perspiration, friction from skin-to-skin contact and the presence of fungi or bacteria. Existing treatment options tend to address only 1 or 2 factors associated with intertrigo. Current treatments, such as antifungal and corticosteroid creams may need to be applied frequently (such as twice daily), whereas InterDry can be left in place for up to 5 days.

Current care pathway

No relevant NICE guidelines for the treatment of intertrigo were identified. Clinical guidance produced by the primary care dermatology society (PCDS) recommends a

3-step approach to the management of intertrigo: prevention and general measures, medical treatment and other treatments.

For prevention, PCDS recommend minimising skin-to-skin friction, reducing heat and moisture around skinfolds and keeping high-risk areas clean and dry. Patients are also advised to wear light, non-constricting, and absorbent clothing and to avoid synthetic fibres. People with obesity are advised to consider weight loss, if possible. The use of absorptive powders, such as talc and cornstarch, are not recommended by PCDS because they can irritate the skin.

Daktacort cream is recommended as a first-line treatment option because it can treat candida and help to reduce inflammation. Short-term use of Trimovate cream should be considered for more substantial inflammation. Further treatment with topical or oral antibiotics, or oral antifungal therapy may be needed and should be guided by results of skin swabs, which aim to identify the organisms present.

Other treatment, such as surgery to remove excess skin, may be needed for patients with moderate-to-severe intertrigo that is difficult to manage.

According to the company, awareness of intertrigo is low among healthcare professionals.

Population, setting and intended user

InterDry is intended to be used for managing intertrigo, a common inflammatory skin condition caused by moisture, heat and friction from skin-to-skin contact. Intertrigo tends to develop in skin folds, most commonly in the groin, under the breast and in the armpits. It can also become infected by fungi (such as *Candida* or dermatophytes) or bacteria (such as staphylococci, streptococci, *Pseudomonas* and *Proteus*, and can include antibiotic-resistant strains such as methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *Staphylococcus aureus*). Symptoms of intertrigo include redness, inflammation and skin erosion, as well as itching or burning, odour and pain. It is more common in people with obesity. Other risk factors include excessive sweating, systemic infection, chronic steroid and antibiotic use, immunosuppression, immobility and diabetes.

The true incidence and prevalence of intertrigo in the UK is currently unknown. European studies report prevalence rates that vary from 6% in hospital patients to 17% in nursing home patients (Mistiaen and van Halm-Walters 2010). Based on the reported prevalence rates across care settings and patient groups, the company estimates that up to 1.2 million

patients are susceptible to intertrigo in the UK.

InterDry can be used in any care setting where people have intertrigo. This includes acute care facilities, community hospitals, hospices, care homes and community care. After brief training by a nurse, patients may apply InterDry themselves. The company provides clinical support and application guides for clinicians and patients on the appropriate and practical use of InterDry.

Costs

Technology costs

InterDry is available as a non-sterile pouch or roll. Costs per unit are £43.07 for the 25 cm × 91 cm pouch and £105.95 for the 25 cm × 366 cm roll (excluding VAT). According to the company, the average cost of managing intertrigo with InterDry is estimated as £63.83, assuming a 73% probability that symptoms are resolved within 5 days. This is based on assumed daily nursing treatment times (15 minutes of cleaning and InterDry by a band 5 nurse) from the expert estimates of 4 tissue viability nurses. This includes the use of approximately 14 cm of InterDry per day for each patient.

Costs of standard care

According to the company, the average cost of managing intertrigo with standard care is estimated as £64.15, assuming a 36% probability that symptoms are resolved within 5 days. This takes the efficacy of standard care from a randomised controlled trial of Daktacort in UK primary care and conservatively assumes treatment with Daktacort cream only (20 minutes of cleaning and Daktacort treatment by a band 5 nurse) from expert estimates of 4 tissue viability nurses. However, application twice every day would be more usual. This includes the use of approximately 4 g per day for each patient of Daktacort cream (£2.49/30 g, BNF).

Resource consequences

InterDry is currently being evaluated in 4 NHS trusts. Adopting InterDry would involve an initial cost increase compared with current treatment options. This could be offset if using InterDry allowed quicker healing, leading to subsequent reductions in the use of dressings, antimicrobials and healthcare resources. There is no comparative clinical evidence relating

to these outcomes.

Economic data are available on the company website. It consists of an unpublished conference abstract and a master's thesis reporting results from a cost-effectiveness analysis of InterDry compared with standard care (as recommended by PCDS) in a UK community care setting. The analysis used a Markov decision model and was based on 2015 to 2016 costs. The cost-effectiveness model was revised by the company in 2019 and this is available on the website as a report and presentation. The analysis shows an estimated cost saving of £0.32 per patient with InterDry compared with standard care. Because of a lack of quality evidence on InterDry and other existing treatments for intertrigo, the model makes a number of conservative assumptions. It only allows for first-line treatment (InterDry compared with Daktacort cream). The resolution rates for InterDry come from a study of patients with hard-to-treat intertrigo whereas the resolution rates for Daktacort come from a study without severity inclusion criteria. Downstream health benefits gained from faster resolution were not captured. All presented economic data have not been peer reviewed.

Regulatory information

InterDry is CE marked as a class III medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Intertrigo is more common in babies and in older people because of reduced immunity, immobilisation, and moisture; age is a protected characteristic under the Equality Act. Intertrigo most often happens in people with obesity (body mass index more than 30 kg/m^2), and the severity of intertrigo is linked to the degree of obesity. It also happens in people with diabetes and those who have a prosthetic limb. Some of these people may be protected under the disability element of the Equality Act because their condition is likely to have long-term adverse effects on their ability to do normal day-to-day activities.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five studies are summarised in this briefing, involving a total of 28 adults with intertrigo.

The studies included in this briefing are 1 prospective, single-arm cohort study (21 people), 2 case series (total of 5 people) and a 2 case reports (1 person each). Study results and information for these unpublished studies have come from a case studies document produced by the company. Three of the studies have been presented at conferences.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence base comes from studies involving a small number of people treated with InterDry. Most of the studies evaluating InterDry are case series or case reports that provide low-level evidence. A multicentre feasibility study (Kennedy-Evans et al. 2007) showed substantial improvements in itching or burning, denudement (loss of skin layers), secondary satellite lesions, redness and odour by day 5. This study did not involve a control group, so the treatment effects should be interpreted with caution. All available studies had a short follow-up duration of about 5 days. A longer duration of follow up may be helpful to understand the rates of intertrigo recurrence after treatment with InterDry. There is currently no available comparative evidence for InterDry, so the benefits of the technology over existing management options remains uncertain. Available clinical evidence has come from patients treated in Canada or the US, so results may not be generalisable to the NHS. Well-designed, larger and longer-term comparative UK studies would be helpful to understand the efficacy of InterDry compared with existing management options for intertrigo in the NHS.

Table 1 Summary of selected studies

Vorbeck (2016)	
Study size, design and location	Case series involving 3 patients with skin conditions resulting from exposure to excessive moisture in skin folds. US.
Intervention and comparator(s)	InterDry. No comparator.
Key outcomes	Patients in this case series were aged between 41 years and 92 years. Intertrigo was present in the abdominal skin fold or under the breast. Patient 1 was a 92-year-old female with intertrigo under both breasts. InterDry was applied with weekly follow up. Symptom improvement was noted at week 2, with complete resolution at week 3. Patient 2 was a 41-year-old female with intertrigo under abdominal skin fold. Complete resolution of symptoms was noted at week 1 follow up. Patient 3 was a 67-year-old female with candidal intertrigo underneath the abdominal skin fold. There was a marked improvement in symptoms at week-1 follow up and complete resolution at 14-day follow up. Overall, the author concluded that InterDry provided effective moisture management and microbial control. The product was well received by both the patient and staff.
Strengths and limitations	Case series was sponsored by the company and provides low-level evidence. Frequency of dressing changes was unclear. Patients were treated in the US therefore results may not be generalisable to the NHS. The study is only available on the company website.
Hill (2016)	
Study size, design and location	Case report of a 66-year-old male with skin fold complications. Canada.
Intervention and comparator(s)	InterDry. No comparator.

Key outcomes	Case report of a 66-year-old, 193-kg male with CHF, a history of COPD, obstructed sleep apnoea, chronic left leg ulcer and morbid obesity who was admitted to hospital for CHF. The patient had begun to experience extreme pain, itching and odour, which had been unsuccessfully treated with creams. Then 7 days after applying InterDry the author reported that redness had resolved, and odour and discomfort had reduced. The patient continued to use InterDry, and at day 17 all symptoms of redness, itching and odour had resolved.
Strengths and limitations	Case report involving 1 patient treated in Canada, representing low-level evidence and limiting generalisability of results to the NHS. Frequency of dressing changes was unclear. The study is only available on the company website.
Patti Haberer (2015)	
Study size, design and location	Case report of an 80-year-old female with intertrigo. US.
Intervention and comparator(s)	InterDry. No comparator.
Key outcomes	Patient had the following medical history: obesity (BMI 30.5), bilateral mastectomy, uncontrolled diabetes, hypertension, hyperlipidemia, and dementia. The patient had a mild case of intertrigo (redness and pain) in the right armpit and a severe case of intertrigo (redness, maceration, satellite lesions, denuded skin at the base of the fold, odour and pain) in an abdominal skin fold. The author reported that InterDry quickly and effectively resolved both cases of intertrigo within 5 days. At day 2, the redness and pain in the armpit was resolved. At day 5 the redness, satellite lesions, odour, denuded area and pain in the abdominal skin fold had resolved. Results were presented at the Southeast Region of the WOCN Society Annual Conference, September 2015.
Strengths and limitations	Case report involving 1 patient treated in the US, representing low-level evidence and limiting generalisability of results to the NHS. Case study was sponsored by the company. The author was a clinical consultant for the company and a family member of the patient.

Kennedy-Evans et al. (2007)	
Study size, design and location	Prospective, single-arm observational study involving 21 people with intertrigo from 2 long-term care centres. US.
Intervention and comparator(s)	InterDry. No comparator.
Key outcomes	Treatment with InterDry statistically significantly reduced itching or burning by day 3 (p=0.0001) and by day 5 (p<0.0001). The numbers of people with maceration reduced from 10 on day 1 to 1 on day 3 and day 5. Five patients had satellite lesions on day 1. On day 3 and day 5, 1 patient had satellite lesions that were improving. All patients entered the study with erythema. There was a statistically significant reduction in erythema by day 3 and day 5 (both p<0.0001). Separated odour significantly reduced by day 3 (p=0.002) and by day 5 (p=0.0034). Closed odour was not statistically analysed. Presented at the 39th WOCN Society Annual Conference, June 2007.
Strengths and limitations	Single-arm study with no control group, treatment effects may need to be interpreted with caution. It involved a small number of people treated in the US therefore results may not be generalisable to the NHS. There was limited information available on study methodology, outcome reporting, baseline demographics and confidence intervals, making it difficult to assess the overall quality of evidence of the study.
Tessling et al. (2007)	
Study size, design and location	Case series involving 2 patients with skin conditions resulting from exposure to excessive moisture. US.
Intervention and comparator(s)	InterDry combined with appropriate topical wound treatment. No comparator.

Key outcomes	Patients in this case series were aged 44 years and 69 years. Patient 1, a 69-year-old male with paraplegia presenting with intertrigo of the interdigital spaces with maceration between toes before intervention. InterDry was applied and changed daily after bathing. Maceration resolved within 3 days of treatment. Patient 2, a 44-year-old male presenting with intertrigo in his armpit, abdominal skin fold and groin folds. The moist skin peeling was improved within 24 hours, with the affected areas completely healed within 1 week. Presented at the 39th WOCN Society Annual Conference, June 2007.
Strengths and limitations	Case study series sponsored by the company and provides low-level evidence. Patients were treated in the US so results may not be generalisable to the NHS. Frequency of dressing changes was only stated for 1 patient.
Abbreviations: BMI, body mass index; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; WOCN, Wound, Ostomy and Continence Nurses Society.	

Recent and ongoing studies

No ongoing or in-development trials were identified. The company states that post-marketing surveillance in the UK is ongoing. This includes a market survey on the usability of InterDry and an observational study evaluating its clinical effectiveness and impact on parameters relating to health economics.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

There were 2 out of 4 specialists who were familiar with or had used this technology before.

Level of innovation

Three of the commentators considered InterDry an innovation while 1 commentator considered it a minor variation to be used with current treatment for selected cases of intertrigo. None of the commentators were aware of any competing technologies indicated for the treatment of intertrigo that have a similar mode of action to InterDry. One commentator noted that there are several other silver-based dressings available, although they are not specifically indicated for intertrigo.

Potential patient impact

Potential patient benefits identified by commentators included the relief of itch, discomfort and odour, a reduction in maceration and moisture lesions, a reduction in the need for topical treatment and in the risk of secondary bacterial infection, as well as the ease of application and the ability to self-treat without needing sterile items or equipment. One commentator noted that the technology would be useful in people with severe chronic ulcerated intertrigo when standard first- and second-line treatments have failed to resolve symptoms. People with intertrigo who have a high body mass index, diabetes, are bed-bound or have limited mobility, have a prosthetic limb, and those with issues of excessive moisture were also identified by commentators as people who would benefit most from treatment with InterDry. Three of the commentators said that the technology has the potential to change the current care pathway by improving clinical outcomes compared with current treatment, and if it was able to prevent relapses and reduce the number of hospital visits. One of the commentators said that there would be fewer visits needed and patients could self-treat in the long term. Another commentator felt that the technology had the potential to simplify the nursing care for affected patients who were immobile or had obesity but would have little impact on the number of hospital visits for simple intertrigo cases.

Potential system impact

Potential system benefits identified by commentators included a reduction in the use of topical treatments such as antifungal and steroid creams, a decrease in the nursing time needed and reduced healing time for chronic severe intertrigo. One commentator thought that the technology would be more cost effective than current treatment. One commentator said that InterDry would cost more than current treatment but thought that costs could be minimised if used in selected patients with chronic difficult-to-treat

intertrigo. Another commentator said the possible cost savings would depend on the frequency of dressing changes. The remaining commentator noted that it was difficult to estimate the cost of current treatment, adding that there is no standard approach to treating intertrigo in the UK. One commentator did not predict a substantial impact on resource from adopting the technology. Another commentator thought it may lead to reduced healthcare visits in the long term because patients would be able to self-manage future incidences by preventing them from happening or treating them at an earlier stage. One commentator thought that the technology could help shift the ongoing management of previous difficult maceration from secondary to primary care, as well as reduce the risk of infection and the need for antibiotics and systemic antifungals. One commentator said that staff training may be needed on how to apply the dressing, as well as how to recognise potential complications of dressings such as contact allergy or irritation. Two of the commentators thought the technology could replace current practice while 2 commentators thought it would be used as well as current treatment options. None of the commentators was aware of any safety concerns about the technology.

General comments

Two commentators thought that the cost of the dressings may prevent the technology from being adopted in the NHS, while the remaining 2 commentators were not aware of any issues that would affect adoption. Securing the dressing, the size of the dressing, possible contact allergy and irritation, as well as areas of intertrigo that could make application of dressings more challenging (such as groin and perianal skin) were identified as potential issues with usability or practical aspects. Most of the commentators highlighted the difficulty in estimating the number of patients for whom InterDry would be suitable. One commentator noted that most patients have mild intertrigo and will manage their condition with simple self-treatment, and the incidence of intertrigo is unclear. Non-sponsored randomised controlled trials, studies with longer follow up, comparative evidence showing superiority over other currently used treatment options, evidence showing the antimicrobial action of its active agents against the microbes that are present on the areas of the skin with intertrigo and data showing the incidence of adverse reactions from use of the product were identified by the commentators as areas of further research needed to address uncertainties in the evidence base. One felt that dressings would be changed more frequently than every 5 days, adding that they would be reluctant to reapply a used dressing after bathing.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr David Fitzgerald, consultant dermatologist chair, Division of Surgery and Tertiary Medicine, Salford Royal NHS Foundation Trust, did not declare any interests.
- Dr Fawad Hussain, consultant dermatologist, Barking, Havering and Redbridge NHS Trust, did not declare any interests.
- Ms Carol Johnson, tissue viability matron, County Durham and Darlington NHS Foundation Trust, did not declare any interests.
- Ms Tracy Clarke, clinical nurse specialist, Guy's and St Thomas' NHS Foundation Trust, did not declare any interests.

Development of this briefing

This briefing was developed for NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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