Evidence Review for Prescribing Clinical Network
Treatment: Emollients
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1. Purpose of the Review
   - To review leave-on emollients (excluding preparations with antimicrobials).
   - To establish a preferred list of products for prescribing that a patient can try to
determine efficacy, tolerability and acceptability, and that also offer good value for
money.

2. Appropriateness
2.1 The patient
   Patients of any age.

2.2 The problem
   Patients present with a range of dry skin disorders that may range from a short-term problem
to a life-long condition:\footnote{1}
   - Dry and scaling skin disorders such as eczema, contact dermatitis, psoriasis and
ichthyosis.
   - Dry skin conditions acquired as a result of exposure to drying products or extreme
environmental conditions.
   - Dry or itchy skin due to the reduced sebum production associated with ageing.

Effects and prognosis
   - The skin acts as a barrier to the external environment as well as providing protection
for the internal environment. Dryness and inflammation of the skin can lead to loss of
its barrier function thus making it more susceptible to allergens, irritants, pathogens,
bacteria and further water loss.\footnote{2,4}
   - Long-term severe dryness and inflammation can be uncomfortable and distressing
for the patient and impact on their wellbeing and confidence.

2.3 The Intervention
   - A leave-on emollient is a substance whose main action is to occlude the skin surface
and to encourage the build-up of water in the stratum corneum.\footnote{2}
   - Products for cleansing the skin (instead of ordinary soap products that may cause
irritation and dryness).

How it works
   Emollients soothe, soften and hydrate the skin. Two modes of action have been described\footnote{1,2,4}:
   - Occlusion - emollients increase the amount of water held in the stratum corneum by
rehydrating the outermost layer of skin thus reducing water loss.
   - For emollients containing humectants, such as glycerol and propylene glycol,
moisture is actively drawn into the stratum corneum from the dermis.

Frequency: Regular and frequent application.
3. Effectiveness

3.1 Expected benefits
- Improve the hydration, suppleness and appearance of dry skin.¹,³
- Restored skin barrier function thus reducing susceptibility to infection, irritants and allergens.³
- Regular use of suitable quantities of emollients will help prevent flare ups of eczema.³
- The appropriate use of emollients may reduce the need for topical corticosteroids in atopic eczema.⁵
- Improved well-being of the patient.

3.2 Side-effects/complications⁶,⁷
- Some formulations contain potential skin sensitisers such as lanolin, preservatives, fragrances and sodium lauryl sulphate. Ointments contain fewer potential irritants than creams and lotions.
- Risk of slippery skin and surfaces when using soap substitutes and bath and shower products.
- Potential fire hazard with paraffin-based emollients in contact with dressings or clothing as they may be easily ignited by a naked flame.
- The use of ointments may exacerbate acne.
- The risk of folliculitis can be reduced by advising the patient to apply the emollient in the direction of hair growth.

3.3 Review of evidence
There is a lack of good quality clinical trials concerning the use of emollients but long-term experience supports their efficacy.¹

4. Choice of emollient
The most important factor in selecting an emollient is to find one that the patient will use. The emollient of choice is the least expensive one that is effective and which the patient finds acceptable and is prepared to use on a regular basis.³ The patient should be involved in choosing a suitable emollient. The initial supply should be for a small pack and, if this proves suitable, a larger quantity can then be prescribed. There is considerable variation in patient response to a particular product, thus making it difficult to compare emollients on a wider basis or to predict how much an individual will benefit.² To maximise benefit, patients should be advised to apply suitable quantities depending on the area of the body being treated.⁵

4.1 Factors to consider when selecting an emollient³,⁶

Patient factors
- Patient preference: tolerability, ease of application, product consistency, acceptability to patient.
- Diagnosed skin condition and past history.
- Severity of dry skin condition: greasy ointments achieve better occlusion than cream-based emollients.
- Previous emollients used and their efficacy.
- Patient age/lifestyle: ease of application if not at home; frequent application may not be possible if patient requires assistance; may require different emollients for different parts of the body (e.g. greasier product for limbs, lighter product for face); richer products in winter to combat drying effects of cold weather and heating.
- Safe usage: fire hazard with paraffin-based emollients; soap substitutes may make skin surfaces slippery.
Product factors
- Indications and potential uses: leave-on emollient, soap substitute, bath/shower product.
- Pharmaceutical form: leave-on emollient (ointment, cream, lotion), bath additive or shower product.
- Formulation: lipid (fats, waxes, oils) content, humectants (urea, glycerol), excipients that may be potential sensitisers.
- Variety of pack sizes available. Small pack for initial supply for the patient to try. Quantity can then be increased once patient confirms product is acceptable.
- Packaging. Ease of use of pump dispenser, screw top container or tube. Potential wastage of product left over in pump dispenser/tube (see 4.2).
- Cost
- Manufacturer's information

National and local guidance
- National guidance e.g. NICE, MHRA
- Published reviews and articles
- Local formularies (acute trusts, wound management)
- Current local practice and feedback about current emollient choices.

4.2 Pump dispensers
- Pump dispensers may be convenient and thought to minimise product contamination but not everyone finds them easy to use.
- It can be difficult for the patient to judge how much emollient they have left with some pump packs.
- It is not possible to empty the entire contents of a pump pack container and the amount wasted (residual volume) varies depending on the type of pump dispenser used. A comparison of some proprietary emollients available in 500g pump dispenser packs showed a variation in residual volume ranging from 2.0% to 30.7%. However a number of manufacturers have now improved the pump dispenser mechanism used thus reducing the amount wasted to approximately 2-3%.

4.3 Methodology
A comprehensive review of leave-on emollients listed in section 13.2.1 of the BNF and other emollient products listed in MIMS and the Drug Tariff was undertaken.

Products identified were divided into categories: ointments, creams, gels, lotions and preparations containing urea. The review took relevant criteria into consideration (as listed in 4.1).

Prescribing data for five Surrey Clinical Commissioning Groups (CCGs) was obtained for the 12 month period (November 2013 - October 2014). The CCGs are East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG and Surrey Heath CCG. Data was analysed to identify the main areas of spend, current trends in prescribing and the effect of the preferred list agreed in July 2012.
5. Prescribing Data

Emollient types by cost in 5 Surrey CCGs
The total annual emollient spend was £1,734,700 (November 2013 – October 2014) for 5 Surrey CCGs (excluding barrier preparations and topical local anaesthetics and antipruritics). Leave-on emollients (including urea preparations) accounted for 73% of the total cost.

Top 20 emollients by cost prescribed by 5 Surrey CCGs

<table>
<thead>
<tr>
<th>Product name</th>
<th>Type of emollient (see key above)</th>
<th>Annual cost (November 2013 – October 2014)</th>
<th>Percentage of total emollient spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Aveeno® cream</td>
<td>Leave-on emollients</td>
<td>£174,728</td>
<td>10.1%</td>
</tr>
<tr>
<td>2 Doublebase® gel</td>
<td>Leave-on emollients</td>
<td>£141,331</td>
<td>8.2%</td>
</tr>
<tr>
<td>3 Zerobase® cream</td>
<td>Leave-on emollients containing urea</td>
<td>£136,759</td>
<td>7.9%</td>
</tr>
<tr>
<td>4 Diprobase® cream</td>
<td>Leave-on emollients containing urea</td>
<td>£130,081</td>
<td>7.5%</td>
</tr>
<tr>
<td>5 Cetraben® cream</td>
<td>Bath, shower and wash products</td>
<td>£89,341</td>
<td>5.2%</td>
</tr>
<tr>
<td>6 Dermol 500® lotion</td>
<td>Bath, shower and wash products</td>
<td>£85,888</td>
<td>5.0%</td>
</tr>
<tr>
<td>7 E45® cream</td>
<td>Bath, shower and wash products</td>
<td>£65,134</td>
<td>3.8%</td>
</tr>
<tr>
<td>8 Epaderm® ointment*</td>
<td>Preparations containing antimicrobials</td>
<td>£58,051</td>
<td>3.4%</td>
</tr>
<tr>
<td>9 Aquamax® cream*</td>
<td>Preparations containing antimicrobials</td>
<td>£55,083</td>
<td>3.2%</td>
</tr>
<tr>
<td>10 Aveeno® bath oil</td>
<td>Preparations containing antimicrobials</td>
<td>£49,149</td>
<td>2.8%</td>
</tr>
<tr>
<td>11 Epaderm® cream</td>
<td>Preparations containing antimicrobials</td>
<td>£45,076</td>
<td>2.6%</td>
</tr>
<tr>
<td>12 Oilatum® Junior Bath Additive</td>
<td>Preparations containing antimicrobials</td>
<td>£41,047</td>
<td>2.4%</td>
</tr>
<tr>
<td>13 Dermol 200® shower emollient</td>
<td>Preparations containing antimicrobials</td>
<td>£38,762</td>
<td>2.2%</td>
</tr>
<tr>
<td>14 Aqueous Cream BP</td>
<td>Preparations containing antimicrobials</td>
<td>£37,390</td>
<td>2.2%</td>
</tr>
<tr>
<td>15 Dermol 600® bath emollient</td>
<td>Preparations containing antimicrobials</td>
<td>£35,273</td>
<td>2.0%</td>
</tr>
<tr>
<td>16 Zerocream®</td>
<td>Preparations containing antimicrobials</td>
<td>£32,827</td>
<td>1.9%</td>
</tr>
<tr>
<td>17 Balneum® Plus cream</td>
<td>Preparations containing antimicrobials</td>
<td>£29,513</td>
<td>1.7%</td>
</tr>
<tr>
<td>18 Oilatum® Plus Bath Additive</td>
<td>Preparations containing antimicrobials</td>
<td>£24,903</td>
<td>1.4%</td>
</tr>
<tr>
<td>19 Oilatum® emollient</td>
<td>Preparations containing antimicrobials</td>
<td>£23,627</td>
<td>1.4%</td>
</tr>
<tr>
<td>20 E45® Itch Relief cream</td>
<td>Preparations containing antimicrobials</td>
<td>£22,688</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

* products with more than one use e.g. leave-on emollient/wash product/ bath additive

The top 20 emollient products represent over 75% of total spend.
6. Recommendations

6.1 Who should be prescribed emollients?
- Patients present with a range of dry skin disorders ranging from short-term problems to a life-long conditions. Emollients are indicated for all dry and/or scaling skin disorders1 and need to be used frequently and in suitable quantities.
- It is recognised that some emollients on repeat prescription are for short-term or self-limiting conditions and are only requested occasionally.
- The priority should be to optimise emollient therapy for patients at risk of requiring further intervention if their chronic skin condition is not adequately managed in primary care.

**Recommendation 1: Short-term or self-limiting skin conditions**
The treatment of short-term or self-limiting dry skin conditions should be considered low priority and patients should be advised of the availability of emollient products over the counter. If this is unacceptable, the patient may be offered a leave-on emollient as an acute prescription.

6.2 Prescribing emollients

**Recommendation 2: Initiating an emollient**
- Prescribe an emollient from the preferred list.
- Prescribe a small pack size as an acute prescription. Authorise repeat prescription only when patient acceptability and appropriate usage is confirmed.
- Consider a multi-use product instead of prescribing separate emollients (leave-on, soap substitute and bath products) e.g. Aquamax® cream, Zeroderm® ointment.

**Recommendation 3: Existing prescribing**
- Review emollients currently prescribed for appropriateness and on-going need.
- If emollient use is still indicated, consider changing to an emollient from the preferred list.
- Consider a multi-use product instead of prescribing separate emollients (leave-on, soap substitute and bath products) e.g. Aquamax® cream, Zeroderm® ointment.

6.3 Which emollient?
Following a comprehensive review, seven emollients have been selected as preferred choices. The rationale for product choice is given in the appendices.

**Recommendation 4: Preferred leave-on emollients**
The following emollients are preferred choices:
- 50:50 Liquid and White Soft Paraffin Ointment NPF
- Zeroderm® ointment
- Zeroguent® cream (rich cream)
- Aquamax® cream (first line cream)
- Zerobase® cream (second line cream)
- Zerodouble® gel
- Aquadrade® cream (contains urea)
PLEASE REFER TO SUBSEQUENTLY AMENDED VERSION OF THIS TABLE IN APPENDIX 7

**Pharmaceutical form of emollient** | **PREFERRED LEAVE-ON EMOLLIENTS (Green status)** | **Percentage emollient (paraffin) content** | **Products not recommended for prescribing (similar to preferred product)**
---|---|---|---
**Ointments**<br>Very greasy ointment<br>Greasy ointment<br>Creams and gels<br>Rich cream<br>Creams<br>Aquamax® cream (first line)<br>Zerobase® cream<br>Gel<br>Zerodouble® gel<br>Lotions<br>Preparation with urea | 50:50 Liquid and White Soft Paraffin Ointment NPF<br>Zeroderm® ointment<br>Zeroguent® cream<br>Aquamax® cream<br>Zerobase® cream<br>Zerodouble® gel<br>Aquadrate® cream<br>None<br>Aquadrate® cream | 100%<br>70%<br>12% + 5% refined soya bean oil<br>28%<br>21%<br>15% + 15% isopropyl myristate<br>Urea 10%<br>Preparations containing urea (note some contain a different concentration of urea and/or additional ingredients): Balneum® cream, Balneum® Plus cream, Calmurid® cream, Dermatronics Once Heel Balm®, E45® Itch relief cream, Eucerin® Intensive cream, Flexitol® Heel Balm, Hydromol® Intensive cream, Nutraplus® cream | Epaderm® ointment<br>Hydromol® ointment<br>Thirty:30® ointment<br>Unguentum M® cream<br>Aqueous Cream BP<br>Diprobase® cream<br>Doublebase® gel, Doublebase® Dayleve gel, isopropyl myristate 15%/liquid paraffin 15% gel

**Recommendation 5: Aqueous Cream BP**
The use of Aqueous Cream BP as a leave-on emollient or soap substitute is not supported due to its poor emollient properties and tendency to cause irritant reactions. There are suitable alternatives available. It is not routinely recommended for prescribing.

**Recommendation 6: Products not recommended for prescribing**
Products not recommended for prescribing are similar to but less cost effective than preferred products and are suitable for review (summarised in the table below).
Appendix 1: Ointments

Ointments are useful for areas of very dry and thickened skin as they are effective at increasing skin hydration and restoring the skin barrier. They are greasy and usually anhydrous thus providing greater occlusion than other leave-on products. Their lipid (emollient) content varies between 70% and 100% and is in excess of that of creams, gels and lotions. When dissolved in water, they are suitable for use as soap substitutes. For patients showing sensitivity to emollients, the use of an ointment may reduce the chance of a further reaction since they do not contain preservatives and have fewer excipients than other types of emollient. However they may be less acceptable to patients because of their greasiness and they may cause folliculitis due to their occlusive action.

Methodology

Twelve emollient ointments were reviewed and classified into two groups:
(i) very greasy ointments containing 100% paraffin
(ii) greasy ointments containing 70-80% paraffin

Product choice

Very greasy ointment: Liquid and White Soft Paraffin Ointment NPF (50:50)

Rationale:
- Consistency - higher proportion of liquid paraffin makes this leave-on emollient easier to spread on sore skin compared to other products containing 100% paraffin.
- Included in all 5 Surrey Acute Trust formularies and Surrey Wound Management Formulary.
- Already established as a Surrey preferred option.

Product choice

Greasy ointment: Zeroderm® ointment

Rationale:
- 3 in 1 product – can be used as a leave-on emollient, soap substitute or bath additive
- Most cost effective of four products of a similar formulation (see table below).
- Epaderm® ointment appears in 4 of 5 Surrey Acute Trust formularies; Zeroderm® ointment contains similar ingredients but is more cost effective.
- Already established as a Surrey preferred option.

Comparison of four ointments of similar formulation:

<table>
<thead>
<tr>
<th>Product</th>
<th>Emollient content</th>
<th>Emulsifier</th>
<th>Basic cost (Drug Tariff March 2015)</th>
<th>Percentage saving if Zeroderm® ointment prescribed (based on 500g pack)</th>
<th>Annual spend for 5 Surrey CCGs (Nov 2014 – Oct 2015)</th>
<th>Potential annual saving if all prescribed as Zeroderm® ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epaderm® ointment</td>
<td>Liquid paraffin 40%; yellow soft paraffin 30%</td>
<td>Cetomacrogol emulsifying wax</td>
<td>125g = £3.85, 500g = £6.53, 1kg = £12.02</td>
<td>37%</td>
<td>£58,051</td>
<td>£21,479</td>
</tr>
<tr>
<td>Hydromol® ointment</td>
<td>Liquid paraffin 40%; yellow soft paraffin 30%</td>
<td>Cetomacrogol emulsifying wax</td>
<td>125g = £2.88, 500g = £4.89, 1kg = £9.09</td>
<td>16%</td>
<td>£3,916</td>
<td>£627</td>
</tr>
<tr>
<td>Thirty:30® ointment</td>
<td>Liquid paraffin 40%; yellow soft paraffin 30%</td>
<td>Emulsifying wax</td>
<td>125g = £3.81, 250g = £4.29, 500g = £6.47</td>
<td>1%</td>
<td>£235</td>
<td>£2</td>
</tr>
<tr>
<td>Zeroderm® ointment</td>
<td>Liquid paraffin 40%; white soft paraffin 30%</td>
<td>Cetostearyl alcohol; polysorbate 60</td>
<td>125g = £2.41, 500g = £4.10</td>
<td>N/A</td>
<td>£17,787</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Prescribing
- Initiation: when a greasy ointment is indicated, initiate Zeroderm® ointment.
- Existing prescribing: review the on-going requirement for an emollient. Prescribe the more cost effective Zeroderm® ointment in preference to Epaderm® ointment / Hydromol® ointment / Thirty:30® ointment.

Potential efficiency savings
- Potential annual saving (based on existing prescribing) for 5 Surrey CCGS = £22,108
- Multi-use product: Zeroderm® ointment is a 3 in 1 product (leave-on emollient/soap substitute/bath additive). Consider this as an option instead of prescribing a separate leave-on emollient, soap substitute and bath additive.
- Additional savings will be achieved if initiation is for Zeroderm® ointment instead of a more costly alternative.
Appendix 2: Creams and rich creams

Creams are less greasy than ointments due to a lower lipid (emollient) content. They tend to be preferred by patients as they are easier to apply and well absorbed into the skin. They are emulsions of oil and water; their formulation necessitating the use of excipients such as preservatives, emulsifiers and pH modifiers which are potential sensitisers.

Rich creams contain an additional lipid and are ranked between creams and ointments in terms of emollient content. The additional lipid included varies between products although there have been no studies identified to compare efficacy and tolerability. They offer a useful option to try before moving to a greasy ointment as their consistency and water miscible characteristics are often more acceptable to patients. They also contain potential sensitisers.

Methodology

Products were classified into two groups for review: (i) rich creams and (ii) creams.

<table>
<thead>
<tr>
<th>Product choice</th>
<th>Rich cream: Zeroguent® cream</th>
</tr>
</thead>
</table>

Rationale:
- Zeroguent® cream is a similar type of product to Unguentum M® cream but is more cost effective.
- Unguentum M® cream is included in 3 Surrey Acute Trust formularies; Zeroguent® cream appears in one.
- Already established as a Surrey preferred option.

Comparison of rich creams

<table>
<thead>
<tr>
<th>Product</th>
<th>Emollient content</th>
<th>Basic cost (Drug Tariff March 2015)</th>
<th>Percentage saving if Zeroguent® cream prescribed (based on 500g pack)</th>
<th>Annual spend for 5 Surrey CCGs (Nov 2014 – Oct 2015)</th>
<th>Potential annual saving if all prescribed as Zeroguent® cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unguentum M® cream</td>
<td>White soft paraffin; liquid paraffin; medium-chain triglycerides/saturated neutral oil</td>
<td>50g = £1.41, 100g = £2.78, 200ml pump pack = £5.50, 500g = £8.48</td>
<td>18%</td>
<td>£10,454</td>
<td>£1,881</td>
</tr>
<tr>
<td>Zeroguent® cream</td>
<td>White soft paraffin; light liquid paraffin; refined soya bean oil</td>
<td>100g = £2.33, 500g = £6.99</td>
<td>N/A</td>
<td>£2,814</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Prescribing:
- Initiation: when a rich cream is indicated, initiate Zeroguent® cream. A rich cream is a useful option for a patient to try before moving to a greasy ointment.
- Existing prescribing: review the on-going requirement for an emollient. Prescribe the more cost effective Zeroguent® cream in preference to Unguentum M® cream.

Potential efficiency savings:
- Potential annual saving (based on existing prescribing) for 5 Surrey CCGS = £1,881
Emollient creams were reviewed in the light of criteria listed in 4.1. Additional consideration was given to the inclusion of parabens, sodium lauryl sulphate, oatmeal extracts and Aqueous Cream BP.

Parabens (p-hydroxybenzoic acid esters)
Parabens are employed in many cosmetic and skincare preparations and act as preservatives. They exhibit protection against a broad range of microorganisms. In 2011 the Danish government banned the use of 4 out of 6 the parabens used in products and restricted the use in the remaining 2 – methyl and ethyl paraben. In light of this and an absence of definitive human risk analysis, it was decided to consider first, those preparations that were free of these additives.

Sodium Lauryl Sulphate (SLS)
Sodium lauryl sulphate has a detergent action. It acts as a surfactant and when used as a leave-on product, it may cause irritation at the site of application. Aqueous Cream BP contains SLS and is no longer recommended for use as a leave on emollient, although its irritant effect is mitigated when it is used as a soap substitute.

Oatmeal extracts
Colloidal oatmeal provides a useful humectant and pH balancing effect on the dermis, some evidence suggests an anti-inflammatory effect. The current cost of treatment precludes us from considering these formulations in this review.

**Aquamax® cream**
Rationale:
- Aquamax® cream is a dual purpose product suitable for use both as a leave-on emollient and a soap substitute.
- It is an alternative to Aqueous Cream BP which is no longer recommended.
- It has a higher emollient content (28% total paraffin) than many creams yet at a competitive cost (£3.99 per 500g).
- Aquamax® cream is listed in one out of five Surrey Acute Trust formularies.
- Already established as a Surrey preferred option.

### Comparison of Aquamax® cream and Aqueous Cream BP

<table>
<thead>
<tr>
<th>Product</th>
<th>Emollient content</th>
<th>Basic cost (Drug Tariff March 2015)</th>
<th>Percentage saving if Aquamax® cream prescribed (based on 500g pack)</th>
<th>Annual spend for 5 Surrey CCGs (Nov 2014 – Oct 2015)</th>
<th>Potential annual saving if all prescribed as Aquamax® cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous Cream BP</td>
<td>White soft paraffin 15%; liquid paraffin 6% (total = 21%)</td>
<td>100g = £0.98, 500g = £4.90</td>
<td>18.5%</td>
<td>£37,390</td>
<td>£6,917</td>
</tr>
<tr>
<td>Aquamax® cream</td>
<td>White soft paraffin 20%; liquid paraffin 8% (total = 28%)</td>
<td>100g = £1.89, 500g = £3.99</td>
<td>N/A</td>
<td>£55,083</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Aqueous Cream BP**
The use of Aqueous Cream BP as a leave-on emollient or soap substitute is not supported due to its poor emollient properties and tendency to cause irritant reactions. It was originally formulated as a soap substitute and not as a leave–on emollient. It has a high
water content (69%) thus making it a less effective emollient for those with dry skin.\textsuperscript{20} Its use as a leave-on emollient may increase the risk of skin reactions, particularly in eczema.\textsuperscript{6} NICE does not recommend the use of Aqueous Cream BP as a leave-on emollient for children with eczema.\textsuperscript{21}

Whilst its formulation is not directly comparable to Aqueous Cream BP, Aquamax\textsuperscript{®} cream offers the following advantages over Aqueous Cream BP:

- It contains 33% more emollient than Aqueous Cream BP.
- It does not contain the detergent, sodium lauryl sulphate, a potential skin irritant.
- It is a dual purpose product; Aqueous Cream BP is no longer considered suitable as a dual use product and should now only be used as a soap substitute.\textsuperscript{6}

**ZeroBase\textsuperscript{®} cream**

Rationale:

- ZeroBase\textsuperscript{®} cream and Diprobase\textsuperscript{®} cream contain similar ingredients. They contain the same total percentage of paraffin emollient, although the proportions of white soft paraffin and liquid paraffin vary.
- ZeroBase\textsuperscript{®} cream is more cost effective than Diprobase\textsuperscript{®} cream.
- Both products are available in 500g pump dispenser packs. According to the manufacturers, residual volume is similar for both products (approximately 2%).
- The hydrating effects of ZeroBase\textsuperscript{®} cream and Diprobase\textsuperscript{®} cream have been shown to be almost identical in terms of the magnitude and duration of the moisturising effect when applied to normal forearm skin.\textsuperscript{22} The study was undertaken by Cutest Systems Ltd on behalf of Thornton and Ross (manufacturer of ZeroBase\textsuperscript{®} cream). The moisturising effect was determined by measuring the change in electrical capacitance in the stratum corneum using a Corneometer. This was a small study involving twenty healthy female subjects.
- Diprobase\textsuperscript{®} cream is listed in three out of five Surrey Acute Trust formularies; ZeroBase\textsuperscript{®} cream is listed in one.
- It is already established as a Surrey preferred option.
- The annual cost of prescribing Diprobase\textsuperscript{®} cream is £130,081; this is 7.5% of the total spend on emollients and the fourth highest spend in 5 Surrey CCGs.
- Since the inclusion of ZeroBase\textsuperscript{®} cream in the preferred list in 2012, its use has increased. At 7.9% of total emollient spend it represents the third highest spend in 5 Surrey CCGs.

### Comparison of Diprobase\textsuperscript{®} cream and ZeroBase\textsuperscript{®} cream

<table>
<thead>
<tr>
<th>Product</th>
<th>Emollient content</th>
<th>Basic cost (Drug Tariff / MIMS March 2015)</th>
<th>Percentage saving if ZeroBase\textsuperscript{®} cream prescribed (based on 500g pack)</th>
<th>Annual spend for 5 Surrey CCGs (Nov 2014 – Oct 2015)</th>
<th>Potential annual saving if all prescribed as ZeroBase\textsuperscript{®} cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diprobase\textsuperscript{®} cream</td>
<td>White soft paraffin 15%; liquid paraffin 6%</td>
<td>50g = £1.28, 500g pump pack = £6.32</td>
<td>17%</td>
<td>£130,081</td>
<td>£22,114</td>
</tr>
<tr>
<td>Zerobase\textsuperscript{®} cream</td>
<td>White soft paraffin 10%; liquid paraffin 11%</td>
<td>50g = £1.04, 500g pump pack = £5.26</td>
<td>N/A</td>
<td>£136,759</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Prescribing
- **Initiation:** when a cream is indicated, Aquamax® cream should be considered the first line choice due to its emollient content and cost effectiveness.
- **Existing prescribing:** review the on-going requirement for an emollient. For non-preferred creams prescribed, consider the use of Aquamax® cream or Zerobase® cream instead.
- **Aqueous Cream BP.** This is not recommended for use as a leave-on emollient or a soap substitute. Aquamax® cream may be prescribed in preference to Aqueous Cream BP.
- **Diprobase® cream** - prescribe the more cost effective Zerobase® cream in preference to Diprobase® cream.

Potential efficiency savings
Potential annual saving (based on existing prescribing) for 5 Surrey CCGs:
- If Aquamax® cream prescribed instead of Aqueous Cream BP = £6,917
- If Zerobase® cream is prescribed in preference to Diprobase® cream = £22,114
- Additional savings will be achieved if initiation is for Aquamax® cream instead of a more costly alternative.
Appendix 3: Gels

Gels are easily applied and have the advantage of combining several emollient ingredients but the disadvantage of a high water content. Only one study has been identified that compares the efficacy of a gel with another type of emollient so ranking gels against other types of leave-on emollients is not straightforward.

### Rationale:
- Zerodouble® gel has recently become available and is a similar product to Doublebase® gel but is more cost effective.
- The annual cost of prescribing Doublebase® gel (as brand and generic) is £141,331; 8.2% of the total spend on emollients and 2nd highest spend in 5 Surrey CCGs.
- Doublebase® gel is included in 3 Surrey Acute Trust formularies; Zerodouble® gel contains similar ingredients but is more cost effective.
- Another product with similar ingredients has been added to the Doublebase® range: Doublebase® Dayleve gel.
- The hydrating effects of these 3 gels have not yet received rigorous assessment. However one study indicates increased tolerability and efficacy for Doublebase® gel when compared with Aqueous Cream BP.
- Residual volume is similar for the Doublebase gel pump dispenser pack (2%) and the Zerodouble® gel top down bottle (2%). No residual volume figures for Doublebase® Dayleve gel were available from the manufacturer although the type of pump pack is similar to that used for Doublebase gel.
- Gels are widely prescribed and acceptable to patients.

### Comparison of gels

<table>
<thead>
<tr>
<th>Product choice</th>
<th>Gel: Zerodouble® gel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
<td>Emollient content</td>
</tr>
<tr>
<td>Doublebase® gel</td>
<td>Isopropyl myristate 15%; liquid paraffin 15%; glycerin</td>
</tr>
<tr>
<td>Doublebase® Dayleve gel</td>
<td>Isopropyl myristate 15%; liquid paraffin 15%; glycerin</td>
</tr>
<tr>
<td>Zerodouble® gel</td>
<td>Isopropyl myristate 15%; liquid paraffin 15%; glycerin</td>
</tr>
</tbody>
</table>

### Prescribing:
- **Initiation:** when a gel is indicated, initiate Zerodouble® gel.
- **Existing prescribing:** review the on-going requirement for an emollient. Prescribe the more cost effective Zerodouble® gel in preference to Doublebase® gel, Doublebase® Dayleve gel or liquid paraffin 15%/isopropyl myristate 15% gel.

### Potential efficiency savings:
- Potential annual saving (based on existing prescribing for brand and generic)) for 5 Surrey CCGS = £21,569
Appendix 4: Lotions

Lotions are poorly effective emollients because they contain the lowest lipid (emollient) content (between 5% and 14% paraffin content) and the highest proportion of water. They are suitable only for mild dryness of the skin and are less effective for managing chronic skin conditions or promoting wound healing when compared to ointments, creams and gels. They may be useful for use on the scalp or other areas of hairy skin.⁶

Product choice:
Lotions are not recommended and no lotions are included in the preferred list

Rationale:
- The use of lotions is not recommended due to their poor emollient properties.
- The preferred choices of emollients (July 2012) did not include a lotion. There have been no requests from healthcare professionals or patients to change this.
- Only one out of 5 Surrey Acute Trusts includes a lotion in their formulary.

Prescribing:
- Initiation: lotions are not recommended for prescribing unless intended for use on the scalp or a hairy area of skin.
- Existing prescribing: Review the on-going requirement for an emollient. Consider an emollient cream from the preferred list instead of a lotion.

Potential efficiency savings:
- The annual cost of prescribing lotions is £28,969; this is nearly 2% of the total spend on emollients in 5 Surrey CCGs.
- One product accounts for most of this cost. The annual spend on Aveeno® lotion is £21,821. It costs £6.66 for 500ml.
Appendix 5: Preparations containing urea and lactic acid

Lactic acid (alpha hydroxy acid) acts as a keratolytic and when applied to the skin breaks down keratin, a protein that forms part of the skin structure. In conditions such as chronic eczema, excessive amounts of keratin causes the skin cells to harden, resulting in the skin becoming thickened and scaly.

Urea acts as a humectant at low concentrations (10%), but is mildly keratolytic at higher strengths. It is used in scaling conditions such as psoriasis and is useful in the elderly. Occasionally, it is employed with corticosteroids to enhance penetration.

Emollients containing additional ingredients, such as urea, lanolin, lauromacrogols and lactic acid, are not generally recommended since the additional ingredients increase the risk of skin reactions. They may be useful in some patients but there is no evidence from controlled trials to support the use of one emollient over another so the benefit of using such products has not been established.

<table>
<thead>
<tr>
<th>Product choice</th>
<th>Urea product: Aquadrate® cream</th>
</tr>
</thead>
</table>

Comparison of Urea containing emollients

<table>
<thead>
<tr>
<th>Product name</th>
<th>Emollient content</th>
<th>Excipients</th>
<th>Basic cost (Drug Tariff March 2015)</th>
<th>Percentage saving if Aquadrate® cream used instead of 5% &amp; 10% urea products</th>
<th>Annual spend for 5 Surrey CCGs (Nov 14 – Oct 15)</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquadrate® cream</td>
<td>urea 10%, white soft paraffin; isopropyl myristate</td>
<td>maize starch, isopropyl myristate, syncrowax HR-C, palmitic acid, sorbitan laurate and araitone G</td>
<td>100g = £4.37</td>
<td>N/A</td>
<td>£432</td>
<td>High urea, no parabens, reasonable cost. Lack of evidence of superiority amongst other similar formulations.</td>
</tr>
<tr>
<td>Balneum® cream</td>
<td>urea 5%, ceramide 0.1%</td>
<td>cetostearyl alcohol; polysorbates; propylene glycol</td>
<td>50g = £2.84 500g = £9.97</td>
<td>N/A</td>
<td>£9,005</td>
<td>Low urea, high cost for 50g</td>
</tr>
<tr>
<td>Balneum® Plus cream</td>
<td>urea 5%, lauromacrogols 3% benzyl alcohol, polysorbates</td>
<td></td>
<td>100g = £3.29 500g = £14.99</td>
<td>N/A</td>
<td>£29,513</td>
<td>Low urea, potential sensitis</td>
</tr>
<tr>
<td>Calmurid Cream®</td>
<td>urea 10% lactic acid 5%</td>
<td></td>
<td>100g = £9.27 500g = £35.70</td>
<td>53%</td>
<td>£19,454</td>
<td>High urea, cost prohibitive</td>
</tr>
<tr>
<td>Dermatonics Once Heel Balm®</td>
<td>urea 25% beeswax, lanolin</td>
<td></td>
<td>75ml = £3.60 200ml = £8.50</td>
<td>N/A</td>
<td>£1,771</td>
<td>Very high urea, higher costs and potential sensitisers. Limited indication for use</td>
</tr>
<tr>
<td>E45® Itch relief cream</td>
<td>urea 5% macrogol lauryl ether 3%, benzyl alcohol, polysorbates</td>
<td></td>
<td>50g = £2.81 100g = £3.74 500g = £14.99</td>
<td>N/A</td>
<td>£22,688</td>
<td>Low urea, potential sensitizer</td>
</tr>
<tr>
<td>Eucerin® Intensive</td>
<td>urea 10% benzyl alcohol, isopropyl palmitate, wool fat</td>
<td></td>
<td>100ml = £7.59</td>
<td>43%</td>
<td>£3,474</td>
<td>High urea, cost prohibitive, potential sensitisers</td>
</tr>
<tr>
<td>Flexitol® Heel Balm</td>
<td>urea 25%</td>
<td>benzyl alcohol, cetostearyl alcohol, fragrance, lanolin</td>
<td>40g = £2.75</td>
<td>N/A</td>
<td>£673</td>
<td>Very high urea, higher costs and potential sensitisers. Limited indication for use</td>
</tr>
<tr>
<td>---------------------</td>
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<td>-------------</td>
<td>------</td>
<td>------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>uae 10%; white soft paraffin; isopropyl myristate</td>
<td>75g = £3.80</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>maize starch, syncrowax HR-C, palmitic acid, sorbitan laurate and arlatone G</td>
<td>200g = £9.40</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500g = £14.75</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromol® Intensive Cream</td>
<td></td>
<td>urea 10%; white soft paraffin; isopropyl myristate</td>
<td>30g = £1.64</td>
<td>Nil</td>
<td>£1,127</td>
<td>High urea, no parabens, reasonable cost. Potential to confuse names with products from same livery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>maize starch, syncrowax HR-C, palmitic acid, sorbitan laurate and arlatone G</td>
<td>100g = £4.37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutraplus® Cream</td>
<td>urea 10%</td>
<td>hydroxybenzoates (parabens), propylene glycol</td>
<td>100g = £4.37</td>
<td>Nil</td>
<td>£161</td>
<td>High urea, reasonable cost. Contains parabens</td>
</tr>
</tbody>
</table>

Prescribing
- Initiation: the use of a urea product should be reserved for patients who have tried several emollients and used them appropriately but there has been poor response to treatment.
- Existing prescribing: review the on-going requirement for an emollient. Consider whether the use of a cream/ointment/gel without an additional ingredient may be appropriate instead of a product containing urea.

Potential efficiency savings
- Potential annual saving (based on existing prescribing) for 5 Surrey CCGs = £11,803. This is calculated on changing 10% urea products to Aquadrate® cream.
- There may be additional savings if reviews of existing prescribing result in a change from a urea product to another less costly emollient.
## Appendix 6: Summary of potential efficiency savings

### Existing Prescribing
Review for the on-going requirement for an emollient

<table>
<thead>
<tr>
<th>Product</th>
<th>Cost effective alternative</th>
<th>Potential annual saving across 5 Surrey CCGs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epaderm® ointment / Hydromol® ointment / Thirty:30® ointment.</td>
<td>Zeroderm® Ointment</td>
<td>£22,108</td>
</tr>
<tr>
<td>Unguentum M® cream</td>
<td>Zeroguent® cream</td>
<td>£1,881</td>
</tr>
<tr>
<td>Aqueous Cream BP</td>
<td>Aquamax® cream</td>
<td>£6,917</td>
</tr>
<tr>
<td>Diprobase® cream</td>
<td>Zerobase® cream</td>
<td>£22,114</td>
</tr>
<tr>
<td>Doublebase® gel / Doublebase Dayleve® gel / generic version</td>
<td>Zerodouble® gel</td>
<td>£21,569</td>
</tr>
<tr>
<td>Preparations containing 10% urea</td>
<td>Aqurade® cream</td>
<td>£11,803</td>
</tr>
<tr>
<td><strong>Total potential annual saving based on existing prescribing</strong></td>
<td></td>
<td><strong>£86,392</strong></td>
</tr>
</tbody>
</table>

### Initiating Prescribing
Initiate a cost effective product from the preferred list
Appendix 7: Second line emollients

The Prescribing Clinical Network requested the addition of a list of second line products within the appendix so that if preferred products are not suitable, an alternative can easily be selected (PCN meeting on 1st July 2015).

The summary table from page 6 has therefore been amended to show preferred second line options.

<table>
<thead>
<tr>
<th>Pharmaceutical form of emollient</th>
<th>FIRST LINE PREFERRED LEAVE-ON EMOLLIENTS</th>
<th>SECOND LINE PREFERRED LEAVE-ON EMOLLIENTS</th>
<th>Products not recommended for prescribing (similar to preferred product)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ointments</strong></td>
<td>Very greasy ointment</td>
<td>White Soft Paraffin BP</td>
<td>Epaderm® ointment, Hydromol® ointment Thirty:30® ointment</td>
</tr>
<tr>
<td></td>
<td>50:50 Liquid and White Soft Paraffin Ointment NPF (100% paraffin content)</td>
<td>White Soft Paraffin BP (100% paraffin content)</td>
<td></td>
</tr>
<tr>
<td><strong>Greasy ointment</strong></td>
<td>Zeroderm® ointment (70% paraffin content)</td>
<td>Emulsifying Ointment BP (70% paraffin content)</td>
<td></td>
</tr>
<tr>
<td><strong>Creams and gels</strong></td>
<td>Rich cream</td>
<td>Zeroguent® cream (12% paraffin + 5% refined soya bean oil)</td>
<td>Unguentum M® cream</td>
</tr>
<tr>
<td></td>
<td>Aquamax® cream (28% paraffin content)</td>
<td>Zerobase® cream (21% paraffin content)</td>
<td>Aqueous Cream BP, Diprobase® cream</td>
</tr>
<tr>
<td></td>
<td>Zerodouble® gel (15% paraffin + 15% isopropyl myristate)</td>
<td>No suitable alternative</td>
<td>Doublebase® gel, Doublebase® Dayleve gel, isopropyl myristate 15%/liquid paraffin 15% gel</td>
</tr>
<tr>
<td><strong>Lotions</strong></td>
<td>Not recommended for prescribing</td>
<td>Not recommended for prescribing</td>
<td></td>
</tr>
<tr>
<td><strong>Preparation with urea</strong></td>
<td>Aquadrade® cream (Urea 10%)</td>
<td>Hydromol Intensive® cream (Urea 10%)</td>
<td>Preparations containing urea (note some contain a different concentration of urea and/or additional ingredients): Balneum® cream, Balneum® Plus cream, Calmurid® cream, Dermatronics Once Heel Balm®, E45® Itch relief cream Eucerin® Intensive cream, Flexitol® Heel Balm, Nutraplus® cream</td>
</tr>
</tbody>
</table>
Rationale for second line options
In the absence of robust comparative data, patient acceptability, composition and cost effectiveness were considered for alternative products.

Very greasy ointment: White Soft Paraffin BP is non-staining and more cost effective than other products with 100% paraffin content.

Greasy ointment: Emulsifying Ointment BP is more cost effective than other products with 70-80% paraffin content.

Rich cream: no similar products available

Cream: Zerobase® cream – see Appendix 2

Gel: no similar products available

Preparations with urea: Hydromol® Intensive Cream contains the same active ingredient but no parabens.
References

15. *International Journal of Toxicology,* 27(Suppl. 4):1-82, 2008. Copyright © American College of Toxicology ISSN: 1091-5818 print / 1092-874X online DOI: i 0.1080/10915810802548359: Final Amended Report on the Safety Assessment of Methyl paraben, Ethyl paraben, Propyl paraben, Isopropyl paraben, Butyl paraben, Isobutyl paraben and Benzyl paraben as used in Cosmetic Product
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<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Status</th>
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<tr>
<td>V1</td>
<td>06/05/2015</td>
<td>Clare Curran, Sanjeev Sudera</td>
<td></td>
<td>Presented to PCN 06/05/2015</td>
</tr>
<tr>
<td>V2</td>
<td>01/07/2015</td>
<td>Clare Curran, Sanjeev Sudera</td>
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<td>Presented to PCN 01/07/2015: Section 6 Recommendations (pages 5&amp;6) amended following PCN comments. 2 page prescribing summary (v1)</td>
</tr>
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<td>07/10/2015</td>
<td>Clare Curran Sanjeev Sudera</td>
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<td>Presented to PCN 07/10/2015: Addition of Appendix 7 following PCN comments. Amendments as requested to 2 page prescribing summary (v2)</td>
</tr>
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