1. **Treatment & Condition**  
Dimethyl fumarate for treating moderate to severe plaque psoriasis.

2. **Associated appraisal body & Summary of ruling**  

Dimethyl fumarate is recommended as an option for treating plaque psoriasis in adults, only if the disease:
- is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10, and
- has not responded to other systemic therapies, including, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated.

Stop dimethyl fumarate treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as:
- a 75% reduction in the PASI score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

When using the DLQI, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.

3. **Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)**  
Using the assumptions included in the Resource Impact Template that accompanies TA475, in Northern Ireland it would be expected that 57 patients would be treated with dimethyl fumarate annually.

4. **Patient Access Scheme Availability**  
(Yes/No)

5. **Costs (before PAS if applicable)**

5.1 **Drug cost per patient per annum (for new and prevalent cases)**  
Dimethyl fumarate (Skilarence®) is given at a maximum dosage of 240mg 3 times
daily given orally, after an initial titration schedule. In the first week, 30mg is taken once daily. In the second week, 30mg is taken twice daily. In the third week, 30mg is taken 3 times daily. From the fourth week, a single 120mg daily dose is given and increased weekly for 5 weeks, until the maximum daily dose is reached.

The list price is £89.04 (excluding VAT) for a titration pack (that is, 42 x 30mg tablets) and £190.80 (excluding VAT) for a pack of 90 x 120mg tablets.

Therefore cost per patient per annum is:
- £2,961.29 in year 1
- £3,049 from year 2 onwards

5.2 Infrastructure costs Per annum

It is anticipated that infrastructure requirements will be minimal.

Infrastructure requirements for the delivery of all specialist dermatology drugs are reviewed annually as part of the routine commissioning arrangements for supporting growth in the provision of these therapies.

6. Expected implementation period

There is no impediment to implementation of this guidance.

7. Commissioning arrangements

This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team / Integrated Care.

This therapy has been adjudicated as an Amber medicine in Northern Ireland and as such, the therapy will be initiated in secondary care with ongoing prescribing in primary care.

8. Monitoring arrangements

The HSC Board has arrangements in place for the monthly monitoring of all specialist dermatology therapies (activity/cost and waiting times). Consideration will be given to the most appropriate arrangement for capturing information on patient numbers and costs where ongoing prescribing is in a primary care setting.

9. DoH (NI) Legislative/Policy Caveats

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.