National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Dimethyl fumarate for treating moderate to severe chronic plaque psoriasis [ID776]

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

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Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	Almirall	Dimethyl fumarate is not a new chemical entity but, if licensed, will be the first licensed fumaric acid ester (FAE) in the UK. Currently FAEs are a recognised and licensed systemic therapy in Germany and are recommended in international guidelines for both induction and long-term treatment of moderate-to-severe chronic plaque psoriasis in adults. In the UK they have been used on an unlicensed basis since 1999. Dimethyl fumarate, once licensed, will provide clinicians and patients with a licensed medicine which has proven clinical efficacy and safety compared with the unlicensed FAEs. In addition, it is anticipated that dimethyl fumarate will be provided at a lower NHS cost than unlicensed FAEs thereby reducing drug costs. Given this background, it is our belief that limited NICE resources would be better spent on an evaluation of dimethyl fumarate in the context of an update	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope. NICE has considered that this technology should be evaluated through a technology appraisal.

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		of the NICE clinical guideline Psoriasis: The Assessment and Management of psoriasis (CG153), which is subject to review in December this year, rather than a single technology appraisal. *References were provided, but not replicated here.*	
	AbbVie	Yes	Thank you for your comment. The NICE team has taken into account the views of consultees, and it was decided that this technology should be evaluated through a technology appraisal.
	Janssen	No comment	Comment noted.
	Novartis	No comment	Comment noted.
	British Association Of Dermatologists	Yes. Even though the drug is routinely used in the UK in many departments, it is relatively high cost and there is probably not equal access to it.	Thank you for your comment. The NICE team has taken into account the views of consultees, and it was decided that this technology should be evaluated through a technology appraisal.

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	Psoriasis Association	Psoriasis is a condition that is very unique to each individual, and a treatment that works for one person may not necessarily work for another. Because of this, the Psoriasis Association is in favour of the widest possible variety of appropriate treatments being available to patients.There is no treatment currently licensed in the UK that is similar to Dimethyl Fumarate and, as such, this represents a new and unique possible option for patients. Therefore, it is our feeling that a NICE appraisal of this treatment is appropriate.	Thank you for your comment. The NICE team has taken into account the views of consultees, and it was decided that this technology should be evaluated through a technology appraisal.
	Psoriasis and Psoriatic Arthritis Alliance	It would appear to be appropriate to be appraised by NICE.	Comment noted.
Wording	Almirall	The anticipated licensed indication of dimethyl fumarate is for the treatment of moderate to severe chronic plaque psoriasis in adults in need of systemic drug therapy. We therefore recommend that the remit be revised as follows: 'To appraise the clinical and cost effectiveness of LAS41008 within its marketing authorisation for treating adult patients with moderate to severe chronic plaque psoriasis who require systemic drug therapy' The anticipated brand name for dimethyl fumarate is [redacted].	Thank you for your comment. The wording of the remit has been amended to include 'chronic', which defines the indication more appropriately. The remit is intended to be broad and include all relevant populations, which the technology might get licensed to.
	AbbVie	Yes	Comment noted.

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	Janssen	No comment	Comment noted.
	Novartis	No comment	Comment noted.
	British Association Of Dermatologists	Yes	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	They appear to be appropriate.	Comment noted.
Timing Issues	Almirall	As stated above we do not feel an appraisal of dimethyl fumarate is the best use of NICE resources and propose that consideration of dimethyl fumarate would be better managed via an update of the NICE clinical guideline for psoriasis (NICE CG 153 Psoriasis: Assessment and Management). *Reference was provided, but not replicated here*	Thank you for your comment. The NICE team has taken into account the views of consultees, and it was decided that this technology should be evaluated through a technology appraisal.
	AbbVie	Non-urgent	Comment noted.
	Janssen	No comment	Comment noted.
	Novartis	No comment	Comment noted.

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	British Association Of Dermatologists	Average Urgency	Comment noted.
	Psoriasis Association	It is our belief that this appraisal is needed, however the fact that LAS41008 is yet to receive UK Marketing Authorisation would mean that this is not yet urgent.	Thank you for your comment. The NICE team has taken into account the views of consultees, and it was decided that this technology should be evaluated through a technology appraisal.
	Psoriasis and Psoriatic Arthritis Alliance	Given the range of therapies available there does not appear to be any particular urgency, although where current therapies do not work alternative treatments are needed for those patients.	Thank you for your comment. The NICE team has taken into account the views of consultees, and it was decided that this technology should be evaluated through a technology appraisal.
Additional comments on the draft remit	Janssen	No comment	Comment noted.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Almirall	FAEs have been used in Germany since 1959 and on a licensed basis since 1994 and are subject to unlicensed use in other markets including the UK where they have been used since 1999. Recent British Association of Dermatologist Biologic Interventions Register (BADBIR) data indicate that 7.6% of patients receiving conventional systemic therapy are currently receiving unlicensed FAEs. Dimethyl fumarate represents a potentially licensed alternative to currently unlicensed FAEs. We therefore believe that, although unlicensed and not included in NICE CG153 Psoriasis: Assessment and Management, any assessment of dimethyl fumarate, whether within a technology appraisal or a clinical guideline, should recognise unlicensed use of FAEs in order to fully reflect the systemic therapies used in UK clinical practice. *References were provided, but not replicated here.*	Thank you for your comment. As discussed as the Scoping Workshop, fumaric acid esters are used without a marketing authorisation in the UK for the treatment of chronic plaque psoriasis. The background section of the scope has been updated
	Janssen	No comment	Comment noted.
	Novartis	The background section does not currently reflect the severity of psoriasis as a disease. Psoriasis is also associated with a significant negative impact on health-related quality of life (HRQoL). Psoriasis impacts on a patient's quality of life in terms of physical impairment, pain, and psychological stress. Patients with psoriasis have a greater risk of significant co-morbidities including cardiovascular disease and metabolic syndrome, obesity and diabetes. *References were provided, but not replicated here.*	Thank you for your comment. The background section is intended to provide a brief overview of the disease. No change to the scope is needed.

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	British Association Of Dermatologists	No comments	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Reflects the condition.	Comment noted.
The technology/ intervention	Almirall	Yes	Comment noted.
	Janssen	No comment	Comment noted.
	Novartis	No comment	Comment noted.
	British Association Of Dermatologists	Yes	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Appears to match the registered trial data.	Comment noted.
Population	Almirall	Dimethyl fumarate will be an alternative treatment in the systemic therapy part of the psoriasis treatment pathway as defined in NICE CG153. In order to reflect this and the anticipated licensed indication the population should be defined as follows: 'Adults with moderate to severe chronic plaque psoriasis who require systemic drug therapy'	Thank you for your comment. The scope has been updated to specify that the relevant population is adults with moderate to severe chronic plaque psoriasis. Further

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		Dimethyl fumarate is likely to be positioned where other oral systemic therapies (acitretin, methotrexate, and ciclosporin) are clinically inappropriate for patients through lack of efficacy, contraindications, tolerability and/or toxicity issues, or patient preference.	specification of the population was not needed.
	Janssen	NICE pathways distinguis between phtotherapy or systemic therapy as first line treatment options and systemic biological therapy that requires previous systemic treatment failure. The European S3-Guidelines on the systemic treatment of psoriasis vulgaris (Update 2015) includes fumairc acid esters as part of the conventional systemic therapy. The wording of this indication/population seems to indicate that this treatment can be use as first line unlike other biologic therapies with restriction in their label for use after PUVA or systemic therapies.	Thank you for your comments. The scope has been updated to specify that the relevant population is adults with moderate to severe chronic plaque psoriasis.
	Novartis	No comment	Comment noted.
	British Association Of Dermatologists	Consider also children and those with psoriatic arthritis.	Thank you for your comment. Including children and people with psoriatic arthritis was considered inappropriate because the clinical trials of dimethyl fumarate included adults with chronic plaque

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			psoriasis, and not children and people with psoriatic arthritis. In addition, the anticipated wording of the marking authorisation is for adults alone.
	Psoriasis and Psoriatic Arthritis Alliance	The definition of 'adults with moderate to severe psoriasis' needs to reflect the trial entry criteria (chronic plaque psoriasis) and the eventual licence indication.	Thank you for your comments. The scope has been updated to specify that the relevant population is adults with moderate to severe chronic plaque psoriasis.
Comparators	Almirall	Dimethyl fumarate will be an alternative treatment in the systemic therapy part of the psoriasis treatment pathway as defined in NICE CG153, and as stated above is likely to be positioned where other systemic therapies are clinically inappropriate for patients through lack of efficacy, contraindications, tolerability and/or toxicity issues, co-morbidities or patient preference. Phototherapy Phototherapy is not a relevant comparator in this part of the pathway, as its use is usually before systemic therapies which are recommended when phototherapy has been ineffective, cannot be used or has resulted in rapid relapse. Phototherapy should therefore be excluded from the list.	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope. Phototherapy is also a relevant comparator, because it is used for

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		Fumaric acid esters FAEs, although unlicensed, should be included as a comparator. Recent British Association of Dermatologist Biologic Interventions Register (BADBIR) data indicate that 7.6% of patients receiving conventional systemic therapy are receiving unlicensed FAEs. Of additional relevance and interest is the fact that the pivotal clinical trial for dimethyl fumarate directly compares dimethyl fumarate to the FAEs licensed in Germany. FAEs are a well recognised alternative therapy for psoriasis and are recommended in current European treatment guidelines for the induction and long-term treatment of patients with moderate to severe chronic plaque psoriasis. It should also be noted that Fumaderm (a licensed FAE available in Germany) was included as an appropriate economic comparator in the Assessment Group report for the NICE appraisal (TA103) of etanercept and efalizumab for the treatment of adults with psoriasis7. The economic analysis performed by the Assessment Group demonstrated that use of Fumaderm prior to etanercept and efalizumab was cost-effective. Infliximab It should be noted that infliximab is used in a different part of the treatment pathway and in a different patient population compared with dimethyl fumarate. Infliximab is recommended for use after systemic therapy and only for patients with very severe psoriasis8. Infliximab will not be a treatment	treating moderate to severe chronic plaque psoriasis. Infliximab was removed from the list of comparators, because it is indicated for people with very severe psoriasis.

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		option for patient population eligible for dimethyl fumarate and hence should not be considered a relevant comparator. Best supportive care In previous NICE appraisals best supportive care has been based on the NICE clinical guideline (NICE CG 153) costing report for the treatment of psoriasis. For costs associated with best supportive care, in the recent NICE appraisal of apremilast, the Evidence Review Group preferred estimates were based on a publication by Fonia et al. (2010) *References were provided, but not replicated here.*	
	AbbVie	We believe that fumaric acid preparations (Fumaderm) are currently being used off-licence in the UK. Their position in the clinical pathway does not appear to have been considered	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope.
	Janssen	See comment above. • Systemic non-biological therapies (including acitretin, ciclosporin, methotrexate, phototherapy with or without psoralen,)	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are

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		Seemed to be the appropiate comparator for this treatment.	relevant comparators to dimethyl fumarate and have been added as comparators in the scope.
	Novartis	biologics and biosimiliar biologic agents	Thank you for your comments. As outlined in the economic analysis section of the scope, the availability and cost of biosimilars should be taken into account in the appraisal.
	British Association Of Dermatologists	Inpatient admission and bed rest is the universal standard of care in this patient group. Yes all relevant comparators have been considered. • Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis? The established treatments for moderate to severe psoriasis are: Phototherapy including UVA and a psoralen (PUVA) Standard Systemic agents such as; Methotrexate, ciclopsorin, acitretin	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope. As outlined in the economic analysis section of the scope, the availability and cost

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		Biological Agents; Enbrel, Humira, Stelara, Cosentyx.I have used their commercial names now to differentiate them for the biosimilars Biosimilar Agents Please note efalizumab (not "efalixumab") has now been withdrawn due to its association with progressive multifocal leukoencephalopathy.	of biosimilars should be taken into account in the appraisal.
	Psoriasis Association	These are the standard treatments currently used in the NHS, although as a number of biosimilars are now available these may also need to be considered. The availability and costs of biosimilars should certainly be taken into account, however as individual treatments themselves. The British Association of Dermatologists recommends that patients are not 'switched' from original biologic to its related biosimilar.Therefore, their availability and cost can only be considered an alternative at treatment commencement - not during treatment. Best supportive care for those in whom biologics are contraindicated or not tolerated is likely to be systemic non-biologics. However,one of the reasons to progress to biologics is contraindication and tolerability issues at the systemic non-biologic stage. Therefore, for a significant proportion of patients, best supportive care will mean topical therapy, possibly including an in-patient stay. This is based on what we hear anecdotally from our interactions with both patients and healthcare professionals. Fumaderm is used off-licence in some UK centres and so this may need to be considered, however, it is not made available to all patients for whom it may be appropriate, and so could not be classified as 'standard'.	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope. As outlined in the economic analysis section of the scope, the availability and cost of biosimilars should be taken into account in the appraisal.
	Psoriasis and Psoriatic Arthritis Alliance	Yes, but apremilast could also be considered to be an appropriate oral comparator.	Thank you for your comment. Apremilast has been added as a

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			comparator in the scope.
Outcomes	Almirall	All the outcomes listed are appropriate.	Comment noted.
	AbbVie	Yes, but they need to be much more specific to enable meaningful comparison with other agents	Thank you for your comment. The list of outcomes has been updated with examples of possible measures.
	Janssen	No comment	Comment noted.
	Novartis	clear skin is the most important outcome for patients i.e. PASI>90 - this should be the outcome used to compare to other therapies for moderate to severe psoriasis included in the appraisal	Thank you for your comment. The list of outcomes has been updated with examples of possible measures.
	British Association Of Dermatologists	This is debatable but they are in line with the other measures used	Comment noted.
	Psoriasis Association	Yes. As health-related quality of life (DLQI) and psoriasis area and severity (PASI) scoring is required to ascertain appropriateness to progress through the psoriasis treament pathway on to biologic treatments, it is essential that both of these outcomes are considered of comparable importance when assessing the treatment concerned. The other outcomes listed related to rate of response, maintenance of response, adverse effects and mortality, as well	Thank you for your comment. The list of outcomes has been updated with examples of possible measures.

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		as consideration of the non-skin aspects of psoriasis (nails, joints, etc) are also of utmost importance.	
	Psoriasis and Psoriatic Arthritis Alliance	Yes, but would urge that PASI75 is not seen as the target for psoriasis treatment, but now as a low entry level with at least PASI90 or clearance seen as the goal of therapy, given the efficacy other therapies are now achieving.	Thank you for your comment. The list of outcomes has been updated with examples of possible measures.
Economic analysis	Almirall	The economic analysis will reflect established models in psoriasis. It is anticipated that the model developed by York for previous NICE appraisals will be utilised and will form the main framework of our economic model. The anticipated timeline of the model will be 10 years in line with previous economic analyses.	Thank you for your comment. No changes to the scope are needed.
	Janssen	No comment	Comment noted.
	British Association Of Dermatologists	None	Comment noted.
	Psoriasis Association	The availability and costs of biosimilars should certainly be taken into account, however as individual treatments themselves. The British Association of Dermatologists recommends that patients are not 'switched' from original biologic to its related biosimilar.Therefore, their availability and cost can only be considered an alternative at treatment commencement - not during treatment.	Thank you for your comment. As outlined in the economic analysis section of the scope, the cost of biosimilars should be taken into account in the appraisal.

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	Psoriasis and Psoriatic Arthritis Alliance	No comments to make.	Comment noted.
Equality and Diversity	Almirall	As stated above FAEs have been used in Germany on a licensed basis since 1994, but in the UK are subject to unlicensed use only. Recent British Association of Dermatologist Biologic Interventions Register (BADBIR) data indicate that 7.6% of patients receiving conventional systemic therapy are receiving unlicensed FAEs. Dimethyl fumarate represents a potentially licensed alternative to current unlicensed FAEs and an opportunity for all patients receiving FAEs to receive a licensed treatment.	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope.
	AbbVie	As no data from the clinical development program has been made public to date it is difficult to determine whether patients from different ethnic minorities, for example, have been included.	Thank you for your comment. The Appraisal Committee will discuss the potential equality considerations related to the use of this technology. No changes to the scope needed.
	Janssen	No comment	Comment noted.

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	British Association Of Dermatologists	Check on the data for children and those sub-groups with psoriatic arthritis as well as psoriasis.	Thank you for your comment. Including children and people with psoriatic arthritis was considered inappropriate because the clinical trials of dimethyl fumarate included adults with chronic plaque psoriasis, and not children and people with psoriatic arthritis. In addition, the anticipated wording of the marking authorisation is for adults alone.
	Psoriasis and Psoriatic Arthritis Alliance	There doesn't appear to be any issues.	Comment noted.
Other considerations	Almirall	Not applicable	Comment noted. The other considerations section of the scope has been updated for additional subgroups. If the evidence allows, the following subgroups will be considered: previous

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			use of systemic non-biological therapy, previous use of biological therapy, severity of psoriasis (moderate, severe).
	AbbVie	It is not clear why sequential biologic therapy would be relevant for this STA	Thank you for your comment. As discussed at the Scoping Workshop systemic biological therapies are a relevant comparator, as they are used for the treatment of moderate to severe chronic plaque psoriasis, however infliximab has been excluded from the list, because that is indicated for a different population, for people with very severe psoriasis only. The other considerations section of the scope has been updated for additional subgroups. If the evidence allows, the

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			following subgroups will be considered: previous use of systemic non-biological therapy, previous use of biological therapy, severity of psoriasis (moderate, severe).
	Janssen	No comment	Comment noted. The other considerations section of the scope has been updated for additional subgroups. If the evidence allows, the following subgroups will be considered: previous use of systemic non-biological therapy, previous use of biological therapy, severity of psoriasis (moderate, severe).
	British Association Of Dermatologists	Children and young people would benefit from access to this drug. It is currently used in some centres to treat this age group	Thank you for your comment. As discussed at the Scoping Workshop, the clinical trials of dimethyl

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			fumarate included adults with chronic plaque psoriasis, and they did not look specifically children. In addition, the anticipated wording of the marking authorisation is for adults alone. The other considerations section of the scope has been updated for additional subgroups. If the evidence allows, the following subgroups will be considered: previous use of systemic non-biological therapy, previous use of biological therapy, severity of psoriasis (moderate, severe).
Innovation	Almirall	Not applicable	Comment noted.
	AbbVie	No.It is a modified formulation of an existing product. Of note there is also a dimethyl fumarate compound approved for use in Multiple sclerosis (Tecfidera - Biogen)	Comment noted. The Appraisal Committee will discuss the potentially innovative

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			nature of this technology. No changes to the scope required.
	Janssen	No comment	Comment noted.
	Novartis	No comment	Comment noted.
	British Association Of Dermatologists	No. It is not a step-change. These drugs are currently used though and are effective. It is currently, regularly in use in most Dermatology departments in the U.K. It is used for both adults and children. It provides another oral agent option in contrast to subcutaneous or intravenous therapies.	Comment noted. The Appraisal Committee will discuss the potentially innovative nature of this technology. No changes to the scope required.
	Psoriasis association	No fumarate-based treatment currently holds a UK Marketing Authorisation for psoriasis. Therefore, this treamtent would be innovative in that it would represent a true alternative option for people with moderate to severe psoriasis. As it is different to all treatments currently-available, it may also represent hope for patients who have exhausted all treatment options currently available to them.	Comment noted. The Appraisal Committee will discuss the potentially innovative nature of this technology. No changes to the scope required.
	Psoriasis and Psoriatic Arthritis Alliance	Not particularly innovative or a step change, might be seen as advantageous as a targeted oral therapy, but dosage of 6 tablets per day in the trial appears to be a bit of a burden, particularly for those who have issues with swallowing.	Comment noted. The Appraisal Committee will discuss the potentially innovative nature of this

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			technology. No changes to the scope required.
Questions for consultation	Almirall	Not applicable – all responses are included above	Comment noted.
	Janssen	No comment	Comment noted.
	Novartis	Have all relevant comparators for DMF been included in the scope? Novartis: biosimiliar agents should be considered Are the subgroups suggested in 'other considerations' appropriate? Novartis: patients naïve to any systemic treatments as well as patients exposed to proior systemic /biologic treatments should be considered. It will be important to demonstrate subgroup analyses for both of these patient groups. Where do you consider DMF will fit into the existing NICE pathway for psoriasis? Novartis: clinical input is needed to advise on the positioning.	Thank you for your comments. As outlined in the economic analysis section of the scope, the availability and cost of biosimilars should be taken into account in the appraisal. The other considerations section of the scope has been updated for additional subgroups. If the evidence allows, the following subgroups will be considered: previous use of systemic non-biological therapy, previous use of biological therapy,

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			severity of psoriasis (moderate, severe).
	British Association Of Dermatologists	• Would infliximab be used as a treatment for the patient population for whom dimethyl fumarate would be a treatment option? No, dimethyl fumarate is likely to be used before biological therapies in the treatment of psoriasis. Infliximab is used for those with very severe psoriasis defined as a DLQI >18 and a PASI ≥20 or in those not responsive to any other treatment modality. • 'How should best supportive care be defined?' Inpatient admission to hospital for bed rest and topical therapies. • Are there any subgroups of people in whom dimethyl fumarate (LAS41008) is expected to be more clinically effective and cost effective or other groups that should be examined separately? Children and young people. It is not clear whether it has a place for those people with psoriatic arthritis. • Where do you consider dimethyl fumarate (LAS41008) will fit into the existing NICE pathway, Psoriasis? It would be an option in line with standard systemic agents and before biological therapies. • Do you consider that the use of dimethyl fumarate (LAS41008) can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? No	Thank you for your comments. As discussed at the Scoping Workshop, infliximab is not a relevant comparator to dimethyl fumarate, as it is licensed for a different population, people with very severe psoriasis. As discussed at the Scoping Workshop, the clinical trials of dimethyl fumarate included adults with chronic plaque psoriasis, and they did not look specifically children. In addition, the anticipated wording of the marking authorisation is for adults alone. The other considerations section of the scope has been updated for additional

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			subgroups. If the evidence allows, the following subgroups will be considered: previous use of systemic non-biological therapy, previous use of biological therapy, severity of psoriasis (moderate, severe).
	Psoriasis association	It is difficult to ascertain where in the psoriasis treatment pathway LAS41008 should fit, due to the fact that it does not have a current UK Marketing Authorisation or published costs. However, it is our understanding that when fumaderm is prescribed for people with psoriasis off-licence, it is at a similar level as other non-biologic systemics. Therefore, current practice may suggest that this would be an appropriate level to consider the insertion of LAS41008. As LAS41008 is different to all currently-available psoriasis treatments, there may be patients further down the treatment pathway, currently on sub-optimal biologics or even best supportive care, who could benefit from this treatment.	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope. Infliximab has been excluded, because it is indicated for a different population, people with very severe psoriasis.
	Psoriasis and Psoriatic Arthritis Alliance	Where will the therapy be prescribed (primary or secondary care)? and where will it be positioned in the treatement pathway?	The treatment pathway for psoriasis has been discussed at the

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			scoping workshop. Please see the updated scope.
Additional comments on the draft scope	Almirall	The history of FAE use in Germany is of particular relevance to any assessment of dimethyl fumarate in an NHS context. In Germany two licensed products Fumaderm® and Fumaderm® Initial have been used since 1994 and are the most commonly prescribed oral therapy for the systemic treatment of moderate to severe chronic plaque psoriasis in patients for whom topical therapy is not indicated. In the UK, as already stated above, FAEs are used on an unlicensed basis with 7.6% of patients on conventional systemic therapy receiving unlicensed FAEs. Dimethyl fumarate represents a licensed alternative to current unlicensed FAEs and an opportunity for all eligible patients to receive a licensed treatment.	Thank you for your comments. As discussed at the Scoping Workshop, fumaric acid esters are relevant comparators to dimethyl fumarate and have been added as comparators in the scope.
	Novartis	Side effects and impact of the treatment on the patient will be important considerations in this appraisal.	The Appraisal Committee will discuss the side effects and impact of treatment on patients during the appraisal.
	Psoriasis and Psoriatic Arthritis Alliance	None	Comment noted.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

- Department of health
- Prizer
- Royal College of Nursing

Comments on the matrix: AbbVie: Biogen Idec should be added to the list as the manufacturers of Fumaderm and Tecfidera.

Comments from Royal College of Physicians: We would like to formally endorse the response submitted by the British Association of Dermatologists.