Application for individual reimbursement of Dupixent® (dupilumab) for severe atopic dermatitis in children 6 – 11 years old

For MMP Use Only	
Case Reference	*Date Received*

Date of Application	Nominated Community Pharmacy (Name & address – *leave blank if uncertain)*

Part 1: Patient Details

Name of patient				
Date of birth				
Address				
GMS / DPS / PPS Number (Please tick and insert number)	GMS	DPS	PPSN	
	Number:			

Part 2: Prescriber Details

Name of prescribing consultant	
Medical Council number	
Contact Details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE-Managed Access Protocol for Dupixent® (dupilumab) when completing part 3 and 4 of this application form

Part 3: Patient Clinical History

Please provide the following information (*please tick which apply and complete requested detail):*

1. Patient has an established diagnosis of atopic dermatitis (as per American Academy of Dermatology criteria, outlined in appendix 1) Yes ☐ No ☐

If yes, how many <u>years</u> ago was this diagnosis confirmed? _____

2. Patient is aged 6 - 11 years at the time of application Yes ☐ No ☐

3. What weight is the patient (in kg, at the time of the application)? _____

4. What initial dosing is requested for this patient?

- <u>Dosing for patients 15 kg to less than 60 kg:</u> Dupixent® 300 mg (one 300 mg injection) on Day 1, followed by 300 mg on Day 15 with a subsequent maintenance dose of **300 mg every 4 weeks**, starting 4 weeks after Day 15 dose ☐

or

- <u>Dosing for patients 60 kg or more:</u> Dupixent® 600 mg (two 300 mg injections) as initial dose with a subsequent maintenance dose of **300 mg every other week** ☐

Please provide the following information regarding the severity of the patient's atopic dermatitis at the time of application:

	Score	Date recorded
EASI (Eczema Area and Severity Index) score		
CDLQI (Children's Dermatology Life Quality Index) score		

Part 4: Patient Medication History

Section 1 and section 2 must be completed.

Section 1: Evidence of inadequate response to least one previously trialled immunosuppressant medicine or immune suppression is clinically inadvisable

For reimbursement approval, option 1, 2 or 3 must be satisfied (please tick which apply and complete requested detail)

Option 1: Patient has had a trial[i] with at least one immunosuppressant medicine[ii] that has resulted in an inadequate response[iii] ☐

[i] an adequate trial of a medicine is defined as treatment of at least three consecutive months in duration
[ii] the current standard of care in severe atopic dermatitis for patients who are candidates for systemic immunotherapy include azathioprine, ciclosporin, methotrexate and mycophenolate mofetil
[iii] an inadequate response is defined as failure to achieve and maintain remission or a low disease activity state

Please provide details:

Immunosuppressant medicine 1	
Dose	
Duration of treatment (include start and stop dates)	

If applicable:

Immunosuppressant medicine 2	
Dose	
Duration of treatment (include start and stop dates)	

If applicable:

Immunosuppressant medicine 3	
Dose	
Duration of treatment (include start and stop dates)	

Option 2: Patient did not tolerate an immunosuppressant medicine and experienced a clinically significant adverse reaction which led to discontinuation of treatment prior to completion of an adequate trial ☐

Please provide details:

Immunosuppressant medicine 1	
Dose	
Duration of treatment (include start and stop dates)	
Provide details of the clinically significant adverse reaction which led to discontinuation prior to completion of an adequate trial	
Was the adverse reaction reported to the Health Products Regulatory Authority (HPRA)? Yes ☐ No ☐ If yes, please provide the date the adverse reaction was reported: _____	

If applicable:

Immunosuppressant medicine 2	
Dose	
Duration of treatment (include start and stop dates)	
Provide details of the clinically significant adverse reaction which led to discontinuation prior to completion of an adequate trial	
Was the adverse reaction reported to the Health Products Regulatory Authority (HPRA)? Yes ☐ No ☐ If yes, please provide the date the adverse reaction was reported: _____	

Option 3: Patients in whom immunosuppressant therapy is clinically inadvisable ☐

Provide details of the immunosuppressant medicine(s) and details of why they are clinically inadvisable, including any supporting evidence:

Section 2: Evidence of utilisation of Best Supportive Care (BSC) for atopic dermatitis

For reimbursement approval, evidence to support the utilisation of BSC must be provided

Please tick to confirm that the patient is currently in receipt of BSC for atopic dermatitis ☐

Please tick which apply and provide relevant details:

BSC type	✓ or ✕	Details including products used, frequency of use, duration of use or any other relevant information
Emollients		
Topical corticosteroids		
Topical calcineurin inhibitors		
Rescue treatments (including high potency topical corticosteroids, topical calcineurin inhibitors and systemic corticosteroids)		

Additional space for supporting information

Completed forms should be returned to:

HSE-Medicines Management Programme,

Email: mmp@hse.ie

Authorisation of Request	
Signature of **Prescribing Consultant**	
Institution	

Data Protection Notice

- The information on this form will be used by the Health Service Executive (HSE) to assess the suitability of the items listed to be provided under Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.
- Details of prescription items dispensed to the named person may be notified to the HSE by the dispensing pharmacist to ensure that the names person receives the items required.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the HSE.
- We may share information with the Department of Health, healthcare practitioners and other healthcare bodies.
- We may also disclose information to other parties if the law requires us to do so.
- The PCRS privacy statement can be located at www.pcrs.ie.

Appendix 1: American Academy of Dermatology criteria for the diagnosis of atopic dermatitis[1]:

ESSENTIAL FEATURES - Must be present:

- Pruritus
- Eczema (acute, subacute, chronic)
    - Typical morphology and age-specific patterns*
    - Chronic or relapsing history

*Patterns include:

1. Facial, neck, and extensor involvement in infants and children
2. Current or previous flexural lesions in any age group
3. Sparing of the groin and axillary regions

IMPORTANT FEATURES - Seen in most cases, adding support to the diagnosis:

- Early age of onset
- Atopy
    - Personal and/or family history
    - Immunoglobulin E reactivity
- Xerosis

ASSOCIATED FEATURES - These clinical associations help to suggest the diagnosis of atopic dermatitis but are too nonspecific to be used for defining or detecting atopic dermatitis for research and epidemiologic studies:

- Atypical vascular responses (e.g. facial pallor, white dermographism, delayed blanch response)
- Keratosis pilaris/pityriasis alba/hyperlinear palms/ichthyosis
- Ocular/periorbital changes
- Other regional findings (e.g. perioral changes/periauricular lesions)
- Perifollicular accentuation/lichenification/prurigo lesions

EXCLUSIONARY CONDITIONS - It should be noted that a diagnosis of atopic dermatitis depends on excluding conditions, such as:

- Scabies
- Seborrheic dermatitis
- Contact dermatitis (irritant or allergic)
- Ichthyoses
- Cutaneous T-cell lymphoma
- Psoriasis
- Photosensitivity dermatoses
- Immune deficiency diseases
- Erythroderma of other causes

[1]Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014; 71: 116-32.