SANOFI GENZYME

REQUEST FOR REPEAT SUPPLY OF DUPILUMAB - EARLY ACCESS SCHEME

Please submit the following **Sanofi Genzyme dupilumab Access form** to MedicalAP@sanofi.com or **Fax: (02) 8666 3305**

Patient initials: _____/_____/_____ **Patient DOB: _____/_____/_____**

Patient Eligibility / Non-Eligibility Criteria

Eligibility Criteria		
Does the Patient meet the inclusion criteria below? **Please check/tick the boxes to indicate all criteria that apply**	**Yes**	**No**
Patient has previously received supply of dupilumab for the treatment of atopic dermatitis under the Sanofi Genzyme Early Access Scheme.		

Non-Eligibility Criteria		
Please check/tick the boxes to indicate all criteria that apply	**Yes**	**No**
Is the patient pregnant or breastfeeding, or planning to become pregnant or breastfeed?		
Does the patient have any known allergy or hypersensitivity to the excipients of the dupilumab product Arginine hydrochloride (25 mM), histidine (20 mM), polysorbate 80 (0.2% (w/v), sodium acetate (12.5 mM), sucrose (5% (w/v)), and water for injections, adjusted to pH 5.9 with acetic acid.		
Does the patient have current or recent (within 12 weeks of the first planned administration of dupilumab) endoparasitic (e.g. helminth) infections, suspected infection, or at high risk for such infections		

The following needs to be documented whilst the patient is receiving dupilumab

EASI score captured at week 16 (Required for the **first** Request for Repeat supply only and not subsequent requests. Not required for OLE* Patients)	
Current EASI score (Required for **each** Request for Repeat supply)	

*OLE = Open Label Extension (Clinical trial patients)

Product	Strength	No. of Units	Dose Prescribed	Length of Supply
dupilumab	**300 mg**	**6 packs of 2 x pre-filled syringes**	**1 x 300 mg injection by subcutaneous injection every other week.**	**6 months***

***Supplied in two shipments, three months apart. The second shipment will be dispatched automatically**

Sanofi will provide, in the first instance, six (6) months' supply of dupilumab valid from the date of signature below. If ongoing treatment is deemed appropriate and additional supply is required, please submit a new request form for review.

Sanofi reserves the right to review, amend and/or cancel dupilumab EAS supply.

Please make your patient aware that your dispensing Pharmacist may charge additional fees for the preparation and dispensing of dupilumab. Sanofi does not cover the costs of this under EAS supply.

SANOFI GENZYME

Treating Physician

Physician Name:		Phone No:
Practice Name:		
Address:		
Suburb:	State:	Post Code:
Email:		

Delivery Details

Contact Name:		**Phone No:**
Practice/Pharmacy Name:		
Address:		
Suburb:	**State:**	**Post Code:**
Email:		

Sanofi is committed to documenting the safety of our medications. We collect information on all adverse events reported in association with our products. Sanofi's Product Safety Department can be contacted on **(02) 8666 2123** or email **ae@sanofi.com.** The information that you provide will be reported to our head office and local government authorities and, if necessary, to other worldwide regulatory organisations.

Physician's Declaration

Conditions to be satisfied for inclusion of the patient into the Early Access Scheme.

The patient described above is currently under my care and I declare the information provided to be true and accurate. I confirm that this patient is a resident of Australia. I request the product dupilumab as I believe there is a medically compelling reason to treat him/her with this drug.

I am aware that dupilumab is not commercially available in Australia, and I agree to administer it to this patient via the Early Access Scheme. I will not be using dupilumab for any purpose other than what is stated here.

I agree to advise the patient that the supply of dupilumab is one of compassionate supply and that Sanofi has the right to review, amend and/or cancel early access scheme at its discretion. I take full medical responsibility for the use of dupilumab with this patient and I will properly inform the patient of this product's risk benefit profile according to Dupixent Product Information.

I have the resources and facilities to educate patients on proper injection technique and storage requirements for dupilumab and commit to providing the patient with this training.

In the event that any Dupilumab stock provided for this patient is not used, I agree that it will be securely destroyed and will not be used for any other purpose. I understand and agree that under no circumstances should any Dupilumab stock supplied pursuant to the Early Access Scheme be used to treat any other patients.

I agree to inform Sanofi Product Safety Department (within 1 business day) of all pharmacovigilance data (e.g. adverse events, serious or non-serious), regardless of the treatment relationship to dupilumab, that occur during the treatment and up to 30 days following discontinuation of the last injection administered.

Completed by: Treating Physician

Name:	
Signature:	**Date: ___/___/____**

Privacy Statement

Sanofi-aventis Australia Pty Ltd ABN 31 008 558 807 ("Sanofi") is bound by the Australian Privacy Principles and will store your Personal Information securely and to the extent required by the Privacy Act 1988 (Cth). Sanofi respects your privacy and will not disclose any of your Personal Information. The Personal Information you provided will be used only for purposes related to this activity. You have the right to access, update or correct your Personal Information.

To find out how and for further information on our Privacy Policy, please visit www.sanofi.com.au/privacy or contact our Privacy Officer via email: privacyofficer.australia@sanofi.com, or by writing to: Privacy Officer, Sanofi, Talavera Corporate Centre Building D 12-24 Talavera Road, Macquarie Park, NSW 2113.

Appendix

Dupixent Precautions and Warnings. Please review the full Product Information.

The Dupixent Product Information includes the following:

- Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if Dupixent will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating Dupixent. If patients become infected while receiving treatment with Dupixent and do not respond to anti-helminth treatment, discontinue treatment with Dupixent until infection resolves.
- Conjunctivitis and keratitis occurred more frequently in subjects who received Dupixent. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.
- Safety and efficacy of Dupixent have not been established in the treatment of asthma. Advise patients with comorbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.
- Safety and efficacy have not been established in allergic or atopic conditions other than atopic dermatitis. Patients with comorbid atopic conditions (such as asthma) should be advised not to adjust their treatment without consultation with their physicians. When discontinuing Dupixent consider the potential effects on other atopic conditions.
- The safety and efficacy of concurrent use of Dupixent with live vaccines has not been studied.
- There are no data on the safety of Dupixent when co-administered with other immunomodulators.
- There are limited amount of data from the use of dupilumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Dupixent should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Like other IgG antibodies, dupilumab is expected to cross the placental barrier.
- There are no specific data on the presence of dupilumab in human milk. But human IgG is known to be excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue Dupixent therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.