CENTRE OF EXCELLENCE IN
SEVERE ASTHMA
Innovative solutions for severe asthma

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CLINICAL RECOMMENDATIONS FOR THE USE OF DUPILUMAB IN SEVERE EOSINOPHILIC ALLERGIC ASTHMA

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ABOUT THE TREATMENT

INTRODUCTION

Dupilumab is an add-on maintenance PBS listed treatment for people with severe uncontrolled eosinophilic asthma or severe allergic asthma (aged 6 years and older). Dupilumab is also indicated and PBS-subsidised as maintenance therapy for people with oral corticosteroid dependent eosinophilic or allergic asthma, or chronic severe atopic dermatitis. It is also indicated for adult patients with chronic rhinosinusitis with nasal polyposis.

CRITERIA FOR PBS ELIGIBILITY

See: https://www.servicesaustralia.gov.au/severe-asthma?context=23021 for any recent changes

Below is the checklist for the initiation of PBS-subsidised treatment in severe asthma

PBS Eligibility Criteria for commencement of Dupilimab(1)

CHECKLIST	
	≥ 6 years old
☐	The patient is treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma
	AND
☐	Under the care of the same physician for 6 months OR Diagnosed by a multidisciplinary severe asthma clinic team
	AND
☐	The patient has not received prior PBS-subsidised biological medicine for severe asthma **OR** The patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma of at least 4 weeks
	AND
☐	The patient has had asthma for at least 12 months
	AND
☐	The patient has a diagnosis of asthma: confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features The patient has a diagnosis of asthma defined by standard clinical features, including: Forced Expiratory Volume in 1 second (FEV1) reversibility ≥ 12% and ≥ 200mL at baseline within 30 minutes after administration of salbutamol (200 to 400 µg) **OR** airway hyperresponsiveness > 20% decline in FEV1 during a direct bronchial provocation test or > 15% decline during an indirect bronchial provocation test **OR** peak expiratory flow (PEF) variability > 15% between the 2 highest and 2 lowest peak expiratory flow rates during 14 days **OR** a diagnosis of asthma from at least 2 physicians experienced in the management of patients with severe asthma.
	AND
☐	The patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; **OR** The patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old
	AND
☐	The patient must have failed to achieve adequate control + with optimised asthma therapy*, despite formal assessment of and adherence to correct inhaler technique, which has been documented * Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND** (ii) treatment with oral corticosteroids, either as daily oral corticosteroid for ≥ 6 weeks OR a cumulative dose of OCS of ≥ 500mg prednisolone equivalent in the previous 12 months OR regular maintenance OCS in the last 6 months with a stable daily OCS dose of 5 to 35 mg day of prednisolone OR equivalent of the 4 weeks prior to commencement of a biological medicine treatment for severe asthma. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. + The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND** (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.
	AND
☐	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma ≥6 months
☐☐ Y / N	Is the patient receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation?

CLINICAL BENEFIT

Dupilumab has demonstrated efficacy in reducing annualized exacerbation rates and the rate of severe exacerbations leading to hospitalizations and/or emergency department visits (2, 3). Additionally, significant increases in pre-bronchodilator FEV1 have been observed in clinical trials evaluating dupilumab (2, 3). Improvements in FEV1 were similar whether patients were receiving medium dose inhaled corticosteroids, high dose inhaled corticosteroids, or oral corticosteroids. Improvements in asthma control and asthma related quality of life have also been observed (2, 3). In regards to oral corticosteroid reduction, treatment with dupilumab has demonstrated greater reductions in daily maintenance oral corticosteroid dose, while maintaining asthma control, compared to placebo (4).

MECHANISM OF ACTION

Dupilumab is a recombinant human IgG4 monoclonal antibody that inhibits interleukin-4 and interleukin-13 signaling by binding to the IL-4Rα subunit shared by the IL-4 and IL-13 receptor complexes. Dupilumab inhibits IL-4 signaling via the Type I receptor (IL4Rα/γc), and both IL-4 and IL-13 signaling through the Type II receptor (IL-4Rα/IL-13Rα).

Blocking the IL-4/IL-13 pathway with dupilumab in patients decreases many markers of Type 2 inflammation, including IgE, periostin, and multiple proinflammatory cytokines and chemokines (e.g., eotaxin, TARC), as well as fractional exhaled nitric oxide (FeNO), a marker of lung inflammation. Blocking the IL-4/IL-13 pathway with dupilumab in humanized animal models has been shown to prevent the downstream actions of these cytokines and chemokines, including goblet cell hyperplasia, airway smooth muscle hyperreactivity, eosinophilic lung inflammation, as well as other lung inflammatory processes, while also preventing lung function impairment. The decrease in eosinophilic lung inflammation occurs despite the presence of normal or increased blood eosinophil levels.

PHARMACODYNAMIC EFFECTS

Consistent with inhibition of IL-4 and IL-13 signaling, dupilumab treatment markedly decreased FeNO and circulating concentrations of eotaxin-3, total IgE, allergen specific IgE, TARC, and periostin in asthma subjects relative to placebo. These reductions in biomarkers of inflammation were comparable for the 200 mg Q2W and 300 mg Q2W regimens. There was near maximal suppression of these markers after 2 weeks of treatment, except for IgE which declined more slowly. These effects were sustained throughout treatment.

SAFETY PROFILE

The safety profile has been extracted from Dupilumab Product Information (PI). For further information refer to the PI (https://www.tga.gov.au/sites/default/files/auspar-dupilumab-180612-pi.pdf)

Dupilumab given at 200 mg or 300 mg once every 2 weeks was generally well-tolerated up to 52 weeks in a phase 3 study (2). In clinical trials involving people with asthma, the most common adverse events associated with dupilumab were injection site reactions (including erythema, oedema, pruritus, pain, and inflammation) and blood eosinophilia (2). Hypersensitivity reactions have also been reported.

PRECAUTIONS

Dupilumab is contraindicated in patients who have known hypersensitivity to dupilumab or any of its excipients.

ADVERSE EFFECTS

HYPERSENSITIVITY

If a systemic hypersensitivity reaction occurs, administration of dupilumab should be discontinued immediately and appropriate therapy initiated. One case of serum sickness-like reaction and one case of serum sickness reaction, both considered serious, have been reported in the atopic dermatitis development program following the administration of dupilumab. Both cases were associated with high titres of ***anti-drug antibody*** to dupilumab. One case of anaphylaxis has been reported in the asthma development program following the administration of dupilumab.

HELMINTH INFECTION

Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if dupilumab will influence the immune response against helminth infections. Treatment of patients with pre-existing helminth infections before initiating dupilumab may be required.

CONJUNCTIVITIS AND KERATITIS

Conjunctivitis and keratitis occurred more frequently in patients with atopic dermatitis who received dupilumab. Conjunctivitis was the most frequently reported eye disorder. Most participants with conjunctivitis recovered or were recovering during the treatment period (see Adverse Effects (Undesirable Effects)). Among people with asthma the frequency of conjunctivitis was low and similar between dupilumab and placebo. Health care provided should advise patients to report new onset or worsening eye symptoms.

EOSINOPHILIC CONDITIONS

A transient elevation of blood eosinophil count can occur with dupilumab use. These events usually, but not always, may be associated with the reduction of oral corticosteroid therapy. Cases of eosinophilic pneumonia and of vasculitis consistent with eosinophilic granulomatosis with polyangiitis have been reported with dupilumab in adult patients who participated in the asthma development program. Transient eosinophilia has been observed in some patients in the in the weeks to months after starting dupilumab (5, 6) with a plausible biological mechanism underlying this around inhibiting eosinophil chemotaxis to the lung without inhibiting bone marrow production of eosinophils. There is a paucity of data on switching from IL-5 blocking agents to dupilumab, which could also exacerbate this phenomenon, particularly if combined with oral steroid weaning. This eosinophilia seems to peak in the first few months of treatment, then subside by ~6-12 months, and seems more common at the higher (300mg) dupilumab dose. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia.

One potential pathway for management would be to monitor eosinophils on starting dupilumab, at 3months, 6months and 12months, and otherwise as clinically indicated.

ACUTE ASTHMA SYMPTOMS OR DETERIORATING DISEASE

Dupilumab should not be used to treat acute asthma symptoms or acute exacerbations.

REDUCTION OF CORTICOSTEROID DOSAGE

Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of therapy with dupilumab. Reductions in oral corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in oral corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

USE IN THE ELDERLY

Of the 1472 patients with atopic dermatitis exposed to dupilumab in a phase 2 dose-ranging study or phase 3 placebo-controlled studies, a total of 67 were 65 years or older. Although no differences in safety or efficacy were observed between older and younger adult atopic dermatitis patients, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients.

Of the 1977 patients with asthma treated with dupilumab, a total of 240 patients were 65 years or older and 39 patients were 75 years or older. Efficacy and safety in this age group was similar to the overall study population.

PAEDIATRIC USE IN ASTHMA

Safety and efficacy in children below the age of 6 years with asthma have not been established.

EFFECTS ON FERTILITY

Fertility studies conducted in male and female mice using a surrogate antibody against IL4Rα showed no impairment of fertility. The no-observed-effect-level (NOEL) was the maximum dose studied, 200 mg/kg/week administered subcutaneously which yielded a high multiple of the exposure (serum AUC) in patients at the recommended dose.

USE IN PREGNANCY (CATEGORY B1)

There are limited data from the use of dupilumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Dupilumab should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Like other IgG antibodies, dupilumab is expected to cross the placental barrier.

In an enhanced pre-and postnatal development study, pregnant cynomolgus monkeys were administered a surrogate antibody against IL-4Rα by subcutaneous injection once weekly at doses up to 100 mg/kg/week, from the beginning of organogenesis to parturition. The surrogate antibody used displayed considerably lower affinity for monkey IL-4Rα compared to dupilumab for human IL-4Rα, but the doses used in the study were sufficient to saturate maternal IL-4Rα receptors throughout the treatment period. No treatment-related effects on embryofetal survival, malformations, or on growth, functional development or immunology were observed in the offspring, monitored from birth through to 6 months of age.

USE IN LACTATION

There are no specific data on the presence of dupilumab in human milk. Human IgG is known to be excreted in human milk. A decision must be made whether to discontinue breastfeeding or to discontinue dupilumab therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

LIVE VACCINES

The safety and efficacy of concurrent use of dupilumab with live vaccines has not been studied.

NON-LIVE VACCINES

Immune responses to vaccination were assessed in a study in which patients with atopic dermatitis were treated once weekly for 16 weeks with 300 mg of dupilumab. After 12 weeks of dupilumab administration, patients were vaccinated with a Tdap vaccine (T cell dependent), and a meningococcal polysaccharide vaccine (T cell-independent) and immune responses were assessed 4 weeks later. Antibody responses to both tetanus vaccine and meningococcal polysaccharide vaccine were similar in dupilumab-treated and placebo-treated patients. No adverse interactions between either of the non-live vaccines and dupilumab were noted in the study.

Patients receiving dupilumab may receive concurrent inactivated or non-live vaccinations.

INTERACTIONS WITH CYP450 SUBSTRATES

In a clinical study of atopic dermatitis patients, the effects of dupilumab on the PK of CYP substrates were evaluated. The data gathered from this study did not indicate clinically relevant effect of dupilumab on CYP1A2, CYP3A, CYP2C19, CYP2D6, or CYP2C9 activity.

OTHER

There are no data on the safety of dupilumab when co-administered with other immunomodulators.

USE WITH OTHER DRUGS FOR TREATMENT OF ASTHMA

An effect of dupilumab on the pharmacokinetics of co-administered medications is not expected.

Based on the population analysis, commonly co-administered medications had no effect on dupilumab pharmacokinetics on patients with moderate to severe asthma.

PROCEDURES

DOSAGE

There are two dosing regimens for dupilumab for severe allergic or severe eosinophilic asthma.

The recommended dose of dupilumab **for adults and adolescents (12 years of age and older) is:**

- Initial dose of 400 mg by subcutaneous injection (two 200 mg injections consecutively in different injection sites) followed by 200 mg given every other week

Patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis for which dupilumab is indicated require high dose therapy

- Initial dose of 600 mg by subcutaneous injection (two 300 mg injections consecutively in different injection sites) followed by 300 mg given every other week. (Dupixent PI Oct 2020)

STORAGE

Store in the refrigerator at 2°C to 8°C in the original carton to protect from light. Do not freeze. Do not expose to heat. Do not shake.

If necessary, pre-filled syringes may be kept at room temperature up to 25°C for a maximum of 14 days. Do not store above 25°C. After removal from the refrigerator, dupilumab must be used within 14 days or discarded.

Do not use after the expiry date stamped on the carton and container label.

BEFORE THE FIRST INJECTION

Initial injections will generally be administered in the specialist's clinic or private rooms, day hospital or day procedure unit, for the first 2 to 3 doses. In some situations, the initiation and continued administration of monoclonal antibodies may be considered in primary care, provided specific conditions are met.

At the time of the initial authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter if the patient is on maintenance oral corticosteroids. For all other patients the initial dose is 400mg followed by 200mg every 2 weeks.

Prior to the first dose, the authority application must be made in PRODA and must include:

(a) a completed authority prescription form; and

(b) a completed uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:

  (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

  (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

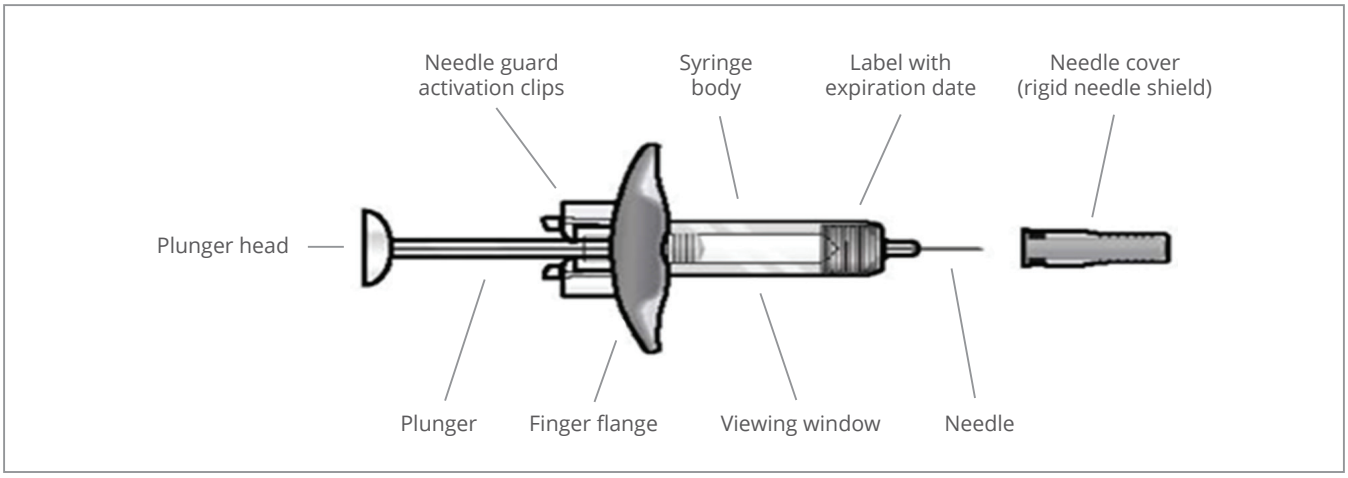
  (iii) the eosinophil count and date; or

  (iv) the IgE result; and

  (v) Asthma Control Questionnaire (ACQ-5) score.

Some exemptions to the above treatment requirements, based on toxicity, are possible. See https://www.humanservices.gov.au/organisations/health-professionals/enablers/severe-asthma-toxicity-criteria-and-severity-descriptors for details.

PREPARATION AND HANDLING



Before injection, remove dupilumab pre-filled syringe from the refrigerator to allow to reach to room temperature (see timing below).

- 300 mg syringe; should be allowed to reach room temperature. Wait for 45 minutes without removing the needle cap.
- 200 mg syringe; should be allowed to reach room temperature. Wait for 30 minutes without removing the needle cap.

Inspect dupilumab visually for particulate matter and discolouration prior to administration. Dupilumab is a clear to slightly opalescent, colourless to pale yellow solution. Do not use if the liquid contains visible particulate matter, is discoloured or cloudy (other than clear to slightly opalescent, colorless to pale yellow).

Dupilumab does not contain preservatives; therefore, discard any unused product remaining in the pre-filled syringe.

The pre-filled syringe should not be exposed to heat or direct sunlight.

Any unused medicinal product or waste material should be disposed. A puncture-resistant container for disposal of syringes should be used and should be kept out of the reach of children.

INJECTION DAY

An assessment of the patient's current asthma and general health should be made before each injection to determine whether there were any recent health changes that might require withholding treatment. This assessment should include vital signs, exacerbation history and spirometry.

Patients should be reminded to continue to take their other asthma medications unless the regimen is changed by their managing physician. Procedure can only take place in an area where there is access to emergency procedures and adequate medical support.

Ensure dupilumab has been prescribed by the respiratory physician on an approved medication chart.

Confirm that the patient has taken their usual asthma medications.

Assess current asthma control and exacerbation status and manage as required. Assess clinical progress by recording medication requirements and changes since last visit.

Perform baseline observations (HR, RR, BP, SpO2 and Temp). Spirometry assessment should be performed at baseline and PBS continuation assessment.

At other visits it may be performed according to the physician's discretion.

Record all information in patient's medical record.

The patient should remain for one hour after the first injection in an area under direct staff observation. It is recommended another two doses are given under medical staff supervision, with an observation period of 30 minutes.

ADMINISTRATION

Dupilumab is intended for use under the guidance of a healthcare provider. The patient's caregiver may administer dupilumab or the patient may self-inject it after guidance has been provided by a healthcare professional on proper subcutaneous injection technique. Provide proper training to patients and/or caregivers on the preparation and administration of dupilumab prior to use according to the instruction leaflet inside the pack.

Allow dupilumab to come to room temperature before injecting.

Do not use the syringe if either the seal on the outer box or the plastic wrapper is broken, as it may be not unsafe for use.

STEPS FOR INJECTION

1. Perform hand hygiene.
2. Prepare a clean, clutter-free work area and position puncture resistant container at point of use.
3. Position patient sitting or lying at a height that ensures there is no need to bend or twist to administer the injection.
4. Remove plastic inner case from cardboard box; remove the peel-back lid.
5. Perform hand hygiene again and put on gloves
6. Grasp the syringe body, not the plunger, to remove prefilled syringe from the tray. Check the expiry date on the syringe. Visually inspect the medication solution for particulate matter and discoloration prior to administration. Do not use if liquid is cloudy, discoloured or if it contains large particles or foreign particulate matter. The syringe may contain a small air bubble; this is normal. Do not expel the air bubble prior to administration.
7. Hold the syringe body and remove the needle cover by pulling straight off. Do not hold the plunger or plunger head while removing the needle cover or the plunger may move. If the prefilled syringe is damaged or contaminated (e.g., dropped without needle cover in place), discard and use a new prefilled syringe.
8. Administer subcutaneous injection into the upper arm, thigh, or abdomen, except for the 5 cm (2 inches) around the navel, using a single-dose pre-filled syringe. Rotate the injection site with each injection.

   DO NOT inject dupilumab into skin that is tender, damaged or has bruises or scars.

   In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
9. Gently pinch the skin and insert the needle at the recommended injection site (i.e., upper arm, thighs or abdomen).
10. Inject all of the medication by pushing in the plunger all the way until the plunger head is completely between the needle guard activation clips. This is necessary to activate the needle guard.
11. After injection, maintain pressure on the plunger head and remove the needle from the skin. Release pressure on the plunger head to allow the needle guard to cover the needle. Do not re-cap the prefilled syringe.
12. If further injections are needed alternate the injection site i.e., other arm, thigh or side of abdomen
13. Dispose of used syringe directly into a puncture resistant container

POST ADMINISTRATION

The patient must be observed directly by a suitably qualified clinician administering the injection for at least one hour after the first dose and 30 minutes thereafter, looking for adverse effects from the medication.

CONTINUATION ASSESSMENT

All applications for continuing treatment with a biological agent must include a measurement of response to the prior course of therapy.

The patient has demonstrated or sustained an adequate response to treatment as evidenced by: a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline; OR; a reduction in the maintenance oral dose of corticosteroid by at least 25% from baseline (with no deterioration in ACQ -5 score from baseline, or no increase from baseline up to 0.5).

This assessment must be made at the time specified in the restriction. Where a response assessment is not undertaken within the required time frame, the patient will be deemed to have failed to respond to treatment with that particular biological agent.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Use this form to apply for continuing PBS subsidised treatment with a biological agent for an adult with uncontrolled severe asthma.

https://www.servicesaustralia.gov.au/organisations/health-professionals/forms/pb076

RECOMMENDATIONS DEVELOPED BY:

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RESOURCES USED

Content reproduced and adapted from the Dupilumab Product Information - http://www.guildlink.com.au/gc/ws/sw/pi.cfm?product=swpdupix

Hunter New England Area Health Clinical Guideline for the Administration and monitoring of respiratory monoclonal antibody medications

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CENTRE OF EXCELLENCE IN

SEVERE ASTHMA

Innovative solutions for severe asthma