Medicines Management Programme

Managed Access Protocol – Medicines for the treatment of severe asthma

Medicine	Date of addition to Managed Access Protocol
Dupilumab (Dupixent®)	01/11/2023
Benralizumab (Fasenra®)	01/12/2025
Mepolizumab (Nucala®)	01/12/2025
Reslizumab (Cinqaero®)	01/12/2025
Tezepelumab (Tezspire®)	01/12/2025

Approved by	**Professor Michael Barry, Clinical Lead, MMP**	
Date approved	Version 1.0	26/10/2023
Date updated	Version 1.1	03/11/2023
	Version 2.0	01/12/2025

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List of abbreviations

ACQ	Asthma Control Questionnaire
ACT	Asthma Control Test
DPI	Dry-powder inhaler
FeNO	Fractional exhaled nitric oxide
HFA	Hydrofluoroalkane propellant
HSE	Health Service Executive
HTH	High Tech Hub
ICS	Inhaled corticosteroids
Ig	Immunoglobulin
IL	Interleukin
IV	Intravenous
kg	Kilograms
LABA	Long-acting $beta_2$-agonist
LAMA	Long-acting muscarinic antagonist
LTRA	Leukotriene receptor antagonist
MAP	Managed Access Protocol
mcg	Micrograms
mg	Milligrams
mL	Millilitres
MMP	Medicines Management Programme
OCS	Oral corticosteroids
PCRS	Primary Care Reimbursement Service
PEFR	Peak expiratory flow rate
PFP	Pre-filled pen
PFS	Pre-filled syringe
ppb	Parts per billion
pMDI	pressurised metered-dose inhaler
SmPC	Summary of Product Characteristics
SC	Subcutaneous
TSLP	Thymic stromal lymphopoietin

1. Medicines for the treatment of severe asthma

There are five biological medicines referenced in this Managed Access Protocol (MAP) for the treatment of severe asthma:

- dupilumab (Dupixent®) and tezepelumab (Tezspire®) are available on the High Tech Arrangement
- benralizumab (Fasenra®) and mepolizumab (Nucala®) are available on the High Tech Arrangement and under Hospital Pricing Approval
- reslizumab (Cinqaero®) is available under Hospital Pricing Approval.

Fasenra® contains benralizumab. Benralizumab is an anti-eosinophil, humanised afucosylated, monoclonal antibody (Immunoglobulin [Ig] G1, kappa). It specifically binds to the alpha subunit of the human interleukin (IL)-5 receptor (IL-5Rα). The IL-5 receptor is specifically expressed on the surface of eosinophils and basophils. The absence of fucose in the Fc domain of benralizumab results in high affinity for FcγRIII receptors on immune effector cells such as natural killer cells. This leads to apoptosis of eosinophils and basophils through enhanced antibody-dependent cell-mediated cytotoxicity, which reduces eosinophilic inflammation.

Hospital Pricing Approval for Fasenra® for the treatment of severe refractory eosinophilic asthma was granted from 1 April 2019. Subsequently, Fasenra® was reimbursed for the treatment of severe refractory eosinophilic asthma on the High Tech Arrangement from 1 October 2021. One presentation of Fasenra® is currently available under Hospital Pricing Approval and on the High Tech Arrangement for the treatment of severe refractory eosinophilic asthma:

- Fasenra® 30 milligrams (mg) solution for injection pre-filled pen (PFP).

Dupixent® contains dupilumab. Dupilumab is a recombinant human IgG4 monoclonal antibody that inhibits IL-4 and IL-13 signalling. Dupilumab inhibits IL-4 signalling via the Type I receptor (IL-4Rα/γc), and both IL-4 and IL-13 signalling through the Type II receptor (IL-4Rα/IL-13Rα). IL-4 and IL-13 are major drivers of human type 2 inflammatory disease, including asthma. Blocking the IL-4/IL-13 pathway with dupilumab decreases many of the mediators of type 2 inflammation.

From 1 November 2023, four presentations of Dupixent® are available on the High Tech Arrangement for the treatment of severe refractory asthma with type 2 inflammation:

- Dupixent® 200 mg solution for injection PFP
- Dupixent® 200 mg solution for injection pre-filled syringe (PFS)

- Dupixent® 300 mg solution for injection PFP
- Dupixent® 300 mg solution for injection PFS.

Nucala® contains mepolizumab. Mepolizumab is a humanised monoclonal antibody (IgG1, kappa), which targets human IL-5 with high affinity and specificity. IL-5 is a major cytokine responsible for the growth and differentiation, recruitment, activation and survival of eosinophils. Mepolizumab inhibits the bioactivity of IL-5 with nanomolar potency by blocking the binding of IL-5 to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface, thereby inhibiting IL-5 signalling and reducing the production and survival of eosinophils.

Two presentations of Nucala® are available under Hospital Pricing Approval (from 13 December 2019) and on the High Tech Arrangement (from 1 October 2021) for the treatment of severe refractory eosinophilic asthma:

- Nucala® 100 mg solution for injection PFP
- Nucala® 100 mg solution for injection PFS.

Cinqaero® contains reslizumab. Reslizumab is a humanised monoclonal antibody (IgG4, kappa) against human IL-5. Reslizumab binds specifically to IL-5 and interferes with IL-5 binding to its cell-surface receptor. Reslizumab binds human IL-5 with picomolar affinity blocking its biological function; consequently survival and activity of eosinophils are reduced.

From 1 April 2019, two presentations of Cinqaero® are available under Hospital Pricing Approval for the treatment of severe refractory eosinophilic asthma:

- Cinqaero® 10 mg/millilitre (mL) concentrate for solution for infusion 2.5 mL vial
- Cinqaero® 10 mg/mL concentrate for solution for infusion 10 mL vial.

Tezspire® contains tezepelumab. Tezepelumab is a monoclonal antibody (IgG2, lamda) directed against thymic stromal lymphopoietin (TSLP), preventing its interaction with the heterodimeric TSLP receptor. In asthma, both allergic and non-allergic triggers induce TSLP production. Blocking TSLP reduces biomarkers and cytokines associated with airway inflammation, e.g. blood eosinophils, airway submucosal eosinophils, IgE, fractional exhaled nitric oxide (FeNO), IL-5, IL-13; however, the mechanism of action in asthma has not been definitively established.

From 1 December 2025, one presentation of Tezspire® is available on the High Tech Arrangement for the treatment of severe refractory asthma with type 2 inflammation:

- Tezspire® 210 mg solution for injection PFP.

1.1 Licensed indications

Benralizumab is indicated as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids (ICS) plus long-acting beta$_2$-agonists (LABA).

Dupilumab is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high-dose ICS plus another medicinal product for maintenance treatment.

Dupilumab is also indicated in children 6 to 11 years as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with medium- to high-dose ICS plus another medicinal product for maintenance treatment.

Mepolizumab is indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged six years and older.

Reslizumab is indicated as add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose ICS plus another medicinal product for maintenance treatment.

Tezepelumab is indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high-dose ICS plus another medicinal product for maintenance treatment.

In addition, benralizumab, dupilumab, mepolizumab and tezepelumab are indicated in the treatment of a number of other disease areas that are outside the scope of this MAP.

1.2 Reimbursement

Reimbursement of benralizumab, dupilumab, mepolizumab and tezepelumab on the High Tech Arrangement and benralizumab, mepolizumab and reslizumab under Hospital Pricing Approval for the treatment of severe asthma is supported for adults (benralizumab, dupilumab, mepolizumab, reslizumab, tezepelumab), adolescents aged 12 years and older (dupilumab, tezepelumab) and children aged 6 to 11 years (dupilumab) who meet the criteria outlined in this MAP. All criteria must be satisfied in order for reimbursement to be supported.

An application for reimbursement approval is required to be submitted on an individual patient basis through the online application system.

Table 1 outlines the licensed therapeutic dosages of the medicines for severe asthma, which are relevant to this MAP. Please refer to the relevant Summary of Product Characteristics (SmPC) for further prescribing information.

Table 1 Licensed therapeutic dosages of medicines for the treatment of severe asthma

Medicine	Patient population	Route of administration	Dosage
Benralizumab	Adults	SC injection	30 mg every four weeks for the first three doses, and then every eight weeks thereafter
Dupilumab	Adults and adolescents aged 12 years and older on oral corticosteroids, or with co-morbid moderate-to-severe atopic dermatitis, or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis	SC injection	Initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week
Dupilumab	All other adults and adolescents aged 12 years and older	SC injection	Initial dose of 400 mg (two 200 mg injections), followed by 200 mg every other week
Dupilumab*	Children aged 6 to 11 years weighing 15 kg to less than 30 kg	SC injection	300 mg every four weeks
Dupilumab*	Children aged 6 to 11 years weighing 30 kg to less than 60 kg	SC injection	200 mg every other week or 300 mg every four weeks
Dupilumab*	Children aged 6 to 11 years weighing 60 kg or more	SC injection	200 mg every other week
Mepolizumab	Adults	SC injection	100 mg every four weeks
Reslizumab	Adults weighing below 35 kg or above 199 kg	IV infusion	3 mg/kg once every four weeks
Reslizumab	Adults weighing between 35 kg and 199 kg	IV infusion	Vial-based dosing scheme as outlined in the SmPC for Cinqaero®
Tezepelumab	Adults and adolescents aged 12 years and older	SC injection	210 mg every four weeks

IV: intravenous; kg: kilograms; mg: milligrams; SC: Subcutaneous injection; SmPC: Summary of Product Characteristics

*For children aged 6 to 11 years with co-morbid severe atopic dermatitis, the recommended dosage of dupilumab is as follows:

- Children aged 6 to 11 years weighing 15 kg to less than 60 kg: an initial dosage of 300 mg on day 1, followed by 300 mg on day 15. A dosage of 300 mg should then be administered every four weeks, starting four weeks after the day 15 dose. This may be increased to 200 mg every two weeks based on physician's assessment.
- Children aged 6 to 11 years weighing 60 kg or more: an initial dosage of 600 mg on day 1, followed by 300 mg every other week.

If a patient is recommended for reimbursement of benralizumab, dupilumab, mepolizumab, reslizumab or tezepelumab, reimbursement is supported in line with the licensed therapeutic dosages as outlined in Table 1. Reimbursement of dosages in excess of the licensed therapeutic dosages (as outlined in Table 1) is not supported.

Reimbursement is not supported for concomitant use of biological medicines for the treatment of severe asthma.

See Section 3 for further details on Reimbursement Criteria – Requirement for outcome data.

1.3 Reimbursement price

The reimbursement prices of the presentations of benralizumab, dupilumab, mepolizumab and tezepelumab available on the High Tech Arrangement are outlined in Table 2. The ex-factory price of the presentations of benralizumab, mepolizumab and reslizumab available under Hospital Pricing Approval are outlined in Table 3. Commercial-in-confidence arrangements are in place with the marketing authorisation holders to reduce the net acquisition cost of these medicines to the Health Service Executive (HSE).

Table 2 Reimbursement codes and prices for the presentations of benralizumab, dupilumab, mepolizumab and tezepelumab available on the High Tech Arrangement

Medicinal product (pack size)	Code	Reimbursement price*
Dupixent® 200 mg PFP (2)	89072	€1,222.06
Dupixent® 200 mg PFS (2)	89074	€1,214.24
Dupixent® 300 mg PFP (2)	89073	€1,226.97
Dupixent® 300 mg PFS (2)	89075	€1,217.83
Fasenra® 30 mg PFP (1)	89108	€1,999.24
Nucala® 100 mg PFP (1)	89101	€1,027.37
Nucala® 100 mg PFS (1)	89102	€1,027.36
Tezspire® 210 mg PFP (1)	89475	€1,181.23

mg: milligrams; PFP: pre-filled pen; PFS: pre-filled syringe
*Correct as at 01/12/2025

Table 3 Ex-factory price for presentations of benralizumab, mepolizumab and reslizumab available under Hospital Pricing Approval

Medicinal product (pack size)	Ex-factory price*
Cinqaero® 10 mg/mL concentrate for solution for infusion 2.5 mL vial (1)	€131.94
Cinqaero® 10 mg/mL concentrate for solution for infusion 10 mL vial (1)	€551.17
Fasenra® 30 mg PFP (1)	€1,851.15
Nucala® 100 mg PFP (1)	€951.27
Nucala® 100 mg PFS (1)	€951.26

mg: milligrams; mL: millilitres; PFP: pre-filled pen; PFS: pre-filled syringe
*Correct as at 01/12/2025

2. Reimbursement criteria - Initiation

This section outlines the criteria that must be satisfied in order for adults, adolescents aged 12 years and older, or children aged 6 to 11 years to be recommended for reimbursement of a medicine for the treatment of severe asthma under the High Tech Arrangement and Hospital Pricing Approval.

2.1 Prescribers

Applications for reimbursement approval for medicines for the treatment of severe asthma under the High Tech Arrangement and Hospital Pricing Approval will only be considered from consultant respiratory physicians or consultant paediatricians with a special interest in respiratory medicine, with specialist registration with the Irish Medical Council in the specialities of respiratory medicine or paediatrics, who specialise in severe asthma and are practicing within a severe asthma centre, and who have agreed to the terms of this MAP and been approved by the HSE ('approved consultants').

Approved consultants are responsible for ensuring that the patient or their representative/guardian is aware that the application for reimbursement approval is being made on their behalf.

The prescribing of Dupixent®, Fasenra®, Nucala® and Tezspire® for approved patients for the treatment of severe asthma under the High Tech Arrangement will be confined to the approved consultants and their teams. The governance of the team on the High Tech Hub, including access, rests with the approved consultant.

The Severe Asthma Advisory Sub-Group of the National Clinical Programme for Respiratory will assist the Health Service Executive (HSE)-Medicines Management Programme (MMP) in identifying

consultant respiratory physicians and consultant paediatricians with a special interest in respiratory medicine, who specialise in severe asthma and are practicing within a severe asthma centre.

2.2 Patient age

Applications for reimbursement approval of medicines for the treatment of severe asthma will only be considered for adults, adolescents 12 years and older, and children aged 6 to 11 years at the time of application.

Table 4 outlines the patient cohorts for which formal HSE reimbursement approval is in place for medicines for the treatment of severe asthma that fall under the scope of this MAP.

Table 4 Patient cohorts for which formal HSE reimbursement is in place for medicines for the treatment of severe asthma

Medicine	Adults*	Adolescents aged 12 years and older	Children aged 6 – 11 years
Benralizumab	✓		
Dupilumab	✓	✓	✓
Mepolizumab	✓		
Reslizumab	✓		
Tezepelumab	✓	✓	

*An adult refers to an individual aged 18 years and older

2.3 Patient diagnosis: Severe Refractory Asthma

Approved consultants are required to confirm a diagnosis of severe refractory asthma with type 2 inflammation (i.e. T2-high population), at the time of application. This diagnosis should be made with reference to the criteria outlined in the National Severe Asthma Network Briefing Paper published by the Severe Asthma Advisory Sub-Group of the National Clinical Programme for Respiratory.

In order for reimbursement of dupilumab or tezepelumab to be supported, patients are required to have a history of one or more of the following biomarkers in the previous 12 months, which are indicative of the presence of type 2 inflammation:

- blood eosinophil count ≥ 300 cells/microlitre (0.3×10^9 cells/litre)
- FeNO ≥ 25 parts per billion (ppb)
- sputum eosinophils ≥ 2%
- asthma that is clinically allergen driven.

In order for reimbursement of benralizumab, mepolizumab or reslizumab to be supported, patients are required to have a blood eosinophil count ≥ 300 cells/microliter (0.3 x 10^9 cells/litre) or sputum eosinophils ≥ 2% in the previous 12 months.

In patients on long-term maintenance oral corticosteroids (OCS) with a blood eosinophil count or FeNO below the thresholds outlined above, a level taken prior to commencement of long-term maintenance OCS should be provided to confirm the presence of type 2 inflammation.

In the case of blood eosinophil levels, FeNO or sputum eosinophils, approved consultants are required to provide the biomarker level and date of corresponding test at the time of application. In the case of asthma that is clinically allergen driven, approved consultants are required to provide relevant information to demonstrate same.

2.4 Patient clinical history/status

In line with the SmPC for Cinqaero®, Dupixent®, Fasenra®, Nucala® and Tezspire®, applications for reimbursement approval will not be considered for individuals who meet any of the contraindications for treatment as outlined in the relevant SmPC.

2.5 Adherence to maintenance treatment

In line with the marketing authorisations of the medicines that fall under the scope of this MAP, patients are required to be in receipt of and fully adherent to an ICS (high-dose ICS in the case of adults and adolescents aged 12 years and older, medium- to high-dose ICS in the case of children aged 6 to 11 years) **plus** another medicinal product for maintenance treatment of their severe asthma, unless evidence is provided to demonstrate the patient has previously been intolerant to such treatment or has a contraindication to treatment.

Table 5 outlines suggested total daily doses that are indicative of treatment with high-dose ICS in adults and adolescents aged 12 years and older, for those corticosteroids that are available in inhaler presentation on the Community Drug Schemes.

Table 5 Total daily dose of inhaled corticosteroid indicative of treatment with high-dose inhaled corticosteroids in adult and adolescents aged 12 years and older

Inhaled corticosteroid	Total daily dose for high-dose ICS (mcg)
Beclomethasone dipropionate (pMDI, standard particle, HFA)	> 1,000
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	> 400
Budesonide (DPI)	> 800
Ciclesonide (pMDI, extrafine particle, HFA)	> 320
Fluticasone furoate (DPI)	200
Fluticasone propionate (DPI)	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	> 500
Mometasone furoate (DPI)	See note below*

DPI: dry-powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroids; mcg: micrograms; pMDI: pressurised metered-dose inhaler

*The classification of high-dose for mometasone furoate (DPI) is dependent on the individual medicinal product. The licensed daily dosage of Atectura® Breezhaler 125 mcg/260 mcg inhalation powder and Enerzair® Breezhaler 114 mcg/46 mcg/136 mcg inhalation powder delivers a quantity of mometasone furoate that would be classified as a high-dose inhaled corticosteroid.

Table 6 outlines suggested total daily doses that are indicative of treatment with medium- to high-dose ICS in children aged 6 to 11 years, for those corticosteroids that are available in inhaler presentation on the Community Drug Schemes.

Table 6 Total daily dose of inhaled corticosteroid indicative of treatment with medium- to high-dose inhaled corticosteroids in children aged 6 to 11 years

Inhaled corticosteroid	Total daily ICS dose (mcg)	
	Medium	High
Beclomethasone dipropionate (pMDI, standard particle, HFA)	> 200 - 400	> 400
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	> 100 - 200	> 200
Budesonide (DPI)	> 200 - 400	> 400
Fluticasone propionate (DPI)	> 100 - 200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	> 100 - 200	> 200

DPI: dry-powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroids; mcg: micrograms; pMDI: pressurised metered-dose inhaler

Medicines that are used in combination with ICS as the other component of maintenance treatment include:

- LABA
- long-acting muscarinic antagonists (LAMA)
- leukotriene receptor antagonists (LTRA)
- OCS.

Approved consultants are required to provide details of the current maintenance treatment for the patient as part of the application for reimbursement approval. Patients must be adherent to a high-dose ICS (adults and adolescents aged 12 years and older) / medium- to high-dose ICS (children aged 6 to 11 years) **plus** another medicinal product as maintenance treatment for a period of at least 12 months at the time of application.

In addition, approved consultants are required to indicate the following:

- confirmation that the patient is fully adherent to maintenance treatment at the time of application
- confirmation that inhaler technique has been assessed, and the patient has been educated on inhaler use
- confirmation that an adherence monitoring programme has been undertaken. This can include some or all of the following elements:

- three consecutive monthly visits to clinical nurse specialist, with provision of adherence advice, review of peak expiratory flow (PEFR) and reported outcomes, or
- digital monitoring of adherence and lung function.

When reviewing applications, the MMP may request evidence to validate that the patient has been in receipt of a high-dose ICS (adults and adolescents aged 12 years and older) / medium- to high-dose ICS (children aged 6 to 11 years) **plus** another medicinal product as maintenance treatment for a period of at least 12 months at the time of application, e.g. printout from community pharmacy of dispensed medicinal products.

2.5.1 Intolerance to maintenance treatment

In cases where a patient did not tolerate a maintenance treatment and experienced a clinically significant adverse reaction which necessitated discontinuation of treatment, information in relation to the medicine, the duration of treatment and the adverse reaction experienced should be provided as part of the application for reimbursement approval. The MMP may request evidence to validate the information provided, e.g. printout from community pharmacy of dispensed medicinal products.

2.5.2 Contraindication to maintenance treatment

For patients in whom maintenance treatment is contraindicated, details of the contraindication, including supporting evidence, should be provided as part of the application for reimbursement approval.

2.6 Inadequate control

Approved consultants are required to provide information to demonstrate that the patient's asthma remains inadequately controlled despite being fully adherent to maintenance treatment for a period of at least 12 months at the time of application.

In order for reimbursement to be supported, patients must either:

- have experienced two or more exacerbations requiring systemic corticosteroids in the 12-month period preceding the date of application, or
- have been taking continuous OCS at a dose ≥ 5 mg of prednisolone daily or equivalent for the six-month period preceding the date of application.

When reviewing applications, the MMP may request evidence to validate that the patient has been in receipt of systemic corticosteroids or continuous OCS, e.g. printout from community pharmacy of dispensed medicinal products.

3. Reimbursement criteria – Requirement for outcome data

Response to treatment with a biological medicine for severe asthma should initially be reviewed by the approved consultant at three-monthly intervals. A definite decision to continue treatment should be made after 12 months of treatment, considering factors such as disease severity and level of exacerbation control. The need for continued therapy should be considered at least on an annual basis as determined by physician assessment of the patient's level of asthma control.

Treatment with a medicine for the treatment of severe asthma should be stopped if the patient's asthma has not responded adequately to treatment.

An adequate response is defined as:

- a clinically meaningful reduction in the number of asthma exacerbations that required systemic corticosteroids or hospitalisation, or
- a clinically significant reduction in continuous OCS use while maintaining improved asthma control.

Therefore, following approval of a patient for reimbursement of a medicine for the treatment of severe asthma under the High Tech Arrangement or Hospital Pricing Approval, the approved consultant may be required to submit follow-up data by secure email to the MMP (mmp@hse.ie). This can include details of response to treatment with the medicine for the treatment of severe asthma, e.g. details of adherence, exacerbations, General Practitioner visits and continuous OCS dose. The approved consultant should also indicate if they intend to continue or discontinue treatment with the medicine for the treatment of severe asthma.

Follow-up data may be requested by the MMP for audit purposes and provision of same is a condition of ongoing reimbursement. It is the responsibility of the approved consultant to ensure that the patient or their representative/guardian is aware that the provision of follow-up data is a condition of reimbursement, and that audits may occur during which their personal data will be reviewed.

4. Prescribing of benralizumab, dupilumab, mepolizumab, reslizumab and tezepelumab for approved patients

Please refer to the relevant SmPC for Fasenra®, Dupixent®, Nucala®, Cinqaero® and Tezspire® for full prescribing information including monitoring and patient counselling requirements.

If a patient is recommended for reimbursement by the MMP, the high tech prescription for benralizumab, dupilumab, mepolizumab or tezepelumab should be generated on the High Tech Hub (HTH). High tech prescriptions that are not hub generated for benralizumab, dupilumab, mepolizumab or tezepelumab will not be eligible for reimbursement by the HSE-Primary Care Reimbursement Service (PCRS). Only approved consultants and their teams will have access to generate prescriptions.