This document provides information on conducting the Spiriva/Spiolto Respimat New To Therapy Program using GuildCare software.

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**Program sponsored by:**

![Boehringer Ingelheim](image1)

Boehringer Ingelheim Pty Limited
78 Waterloo Road
North Ryde, NSW 2113 Australia

**Program powered by:**

![guildcare](image2)
Executive Summary

Program Objective: to inform and support new to therapy Spiriva/Spiolto Respimat patients in achieving optimal long-term treatment outcomes.

Patient Qualification and Notification: Using dispensing history, the GuildCare software will automatically detect patients who have an original or deferred ‘5/0’ prescription and the ‘5/1’ first repeat. A pop-up notification will occur at the point of dispensing.

Enrolment: Pharmacy staff have seven days from notification to validate and invite the patient to enrol in the program. After seven days the invitation will be removed from the GuildCare software until another qualifying Spiriva/Spiolto Respimat prescription is dispensed by the pharmacy. If pharmacy staff do not action after the second invitation, the patient will no longer qualify.

Clinical Service: The clinical service is conducted with the patient over a maximum of two sessions in the pharmacy. These sessions are documented in the GuildCare software.

Program Structure

- **Day 0: Enrolment**
  - Invite patient into program.
  - Provide patient with Spiriva/Spiolto Respimat CMI and discuss potential risks of the medicine.
  - Provide patient with ‘Privacy Policy and Terms of Use’ then indicate they have read and agreed.

- **Day 0: Session 1 (in pharmacy)**
  - Invite patient to receive either SMS reminders and/or follow-up session via phone call.
  - Show patient the Spiriva/Spiolto Respimat videos and assess patient inhaler technique.
  - Discuss information about Spiriva/Spiolto Respimat and when the patient plans to use their medication daily.
  - Automatic claim submission occurs once case is saved as ‘Conducted’. Your pharmacy will receive up to $10 per service if patient opts-in to either the SMS reminders AND/OR the follow-up phone call. Otherwise, the pharmacy will receive $8 per service if no follow-up options are selected.

- **Day 20-40: Session 2 (in pharmacy)**
  - Ask patient questions around Spiriva/Spiolto Respimat adherence.
  - Discuss any other questions the patient may have about their Spiriva/Spiolto Respimat.
  - Automatic claim submission occurs once case is saved as ‘Conducted’. Your pharmacy will receive $4 per service.

- **Day 41: Follow-up phone call (GuildCare Pharmacist Support Centre)**
  - Call is only scheduled if patient has opted-in to this service AND did not receive Session 2 (in pharmacy) between Day 20-40.
  - Follow-up phone calls are conducted by GuildCare pharmacists on behalf of your pharmacy. There is no cost to you.

- **Day 3, 25, and 32: SMS Reminders (GuildCare)**
  - Up to 3 SMS reminders are automatically sent via GuildCare on behalf of your pharmacy. There is no cost to you.
Program Information
Use this protocol document for detailed information about the program rules, content and what to do when conducting the program with patients.

Program Objective
The objective of this program is to inform and support patients who are new to therapy with Spiriva/Spiolto Respimat in achieving optimal long-term treatment outcomes.

Program Overview

Figure 1: Session 1 overview

Figure 2: Session 2 overview
As part of delivering the Spiriva/Spiolto Respimat New To Therapy Program, pharmacists are under obligation to adhere to the relevant professional practice standards. This includes but is not limited to applying professional judgement to identify, record and report potential or actual medication related problems that are likely to be clinically significant for the patient (e.g. interactions, contraindications, incompatibilities, allergies, adverse drug reactions) to the patient’s Medical Practitioner, the Therapeutic Goods Administration and any other relevant entity. See Appendix A: How to report a problem with a medicine or medical device to the Therapeutic Goods Administration.

Facilities to support the program

Each program session should be conducted in an area of privacy where confidential discussions with a patient can be conducted and not overheard by other patients at normal speaking levels, much like usual counselling. This should not be within the dispensary. Ideally this area would also have access to a computer with GuildCare installed, so the Spiriva/Spiolto Respimat videos can be shown to the patient.
Software Information

Staff use the GuildCare software for:

- **Detection** of a qualifying patient (Pop-up notification)
- **Delivery** of the service (Print or complete onscreen)
- **Documentation** of the service (Documentation Tab)

Patient Qualification and Notification

GuildCare software is installed on the pharmacy’s computer(s) and ‘talks’ to your dispensing software. It detects patients who may qualify for the program automatically by analysing their dispensing records at your pharmacy. It does not link with any other pharmacy.

Patients can only enrol in the program if the GuildCare software detects that they qualify. Patients cannot be enrolled ‘ad-hoc’ into this program.

**Patients qualify if they:**

1. are picking up an original prescription or ‘5/0’ deferred supply of Spiriva/Spiolto Respimat;
2. are picking up the ‘5/1’ first repeat prescription of Spiriva/Spiolto Respimat (if program invitation was not actioned during the original dispensing).

A GuildCare pop-up notification alerts pharmacy staff when a patient qualifies for this program. The pharmacy may open the notification immediately or view later in the ‘Patients’ tab of the GuildCare software. Pharmacy staff have seven days from notification to validate and invite the patient to enrol in the program after which the invitation will be removed from the GuildCare software until another qualifying Spiriva/Spiolto Respimat prescription is dispensed by the pharmacy. If pharmacy staff do not action after the second invitation, the patient will no longer qualify.

Patient Consent and Enrolment

Upon notification, confirm with the patient that this is a new therapy for them. Based on their response, if the program is appropriate and the patient consents, then invite them to enrol in the program. Before consent is asked for, the patient must have the capacity to understand what the program provides and how their personal information will be handled. Before enrolment, patient must be provided with a Spiriva/Spiolto Respimat Consumer Medicine Information (CMI) leaflet and the Privacy Policy and Terms of Use.

To confirm their understanding they must also be given the opportunity to ask any questions about the medication or the program. Once consent is gained, it is actioned by ticking the box to verify you have provided this information and obtained patient consent. Patients can consent to some or all services offered in this program. See Clinical Services Information for more details.

Patient Decline

If the patient does not qualify or declines to participate at any time, the pharmacist sets the case status as 'Declined' in the GuildCare software.
Clinical Service Information

The time spent between the pharmacist and the patient in each session is at the discretion of the pharmacist. As a guide, pharmacists may take around five to ten minutes to complete each session. SMS reminders and the follow-up phone call are conducted by GuildCare on behalf of your pharmacy, and are optional depending on patient consent. Please read the “Spiriva/Spiolto Respimat Pharmacist Info” leaflet (link inside program) for more information about Spiriva/Spiolto Respimat before delivering the service.

Enrolment

To enrol the patient in the program, pharmacy staff must complete the following:

- Patient is:
  - Informed they qualify for a free patient support program sponsored by Boehringer Ingelheim
  - Provided with a Spiriva/Spiolto Respimat Consumer Medicine Information leaflet (CMI) and an explanation of the potential risks of the medicine as per the Medicines Australia Code of Conduct
  - Provided with the Privacy Policy and Terms of Use, and then gives their consent to participate in the services offered in the program. This consent is recorded in the GuildCare software by ticking the box “Patient has read and agreed to Privacy Policy and Terms of Use”.

Session 1 – conducted by pharmacy

Community Pharmacist Services

Simply follow the GuildCare documentation tab while delivering the service;

Follow-Up Options

- Invite the patient to receive SMS reminders and/or a follow-up phone call by a GuildCare pharmacist
- Record the patient’s contact number(s) if they consent

Let’s watch a quick video that demonstrates the correct way to use your Spiriva/Spiolto Respimat inhaler

- Show patient the videos
  - Preparing your Respimat Inhaler for first-time use each month
  - How to use your Respimat Inhaler (T.O.P)

Now it’s your turn!

- Ask the patient to demonstrate the steps they would take to use their Spiriva/Spiolto Respimat inhaler while using the two checklists to assess their technique and understanding

Understanding your Medicine

- Discuss with the patient:
  - What their medicine is for
  - How the medicine works
  - How to clean and store the inhaler
- Ask the patient what time of the day they plan to use their Spiriva/Spiolto Respimat daily
- Remind the patient when their next prescription is due

Pharmacist Recommendation

- Record any personal comments and recommendations for patient.
- Tick box to indicate that the service has been completed in accordance with the program protocol.

After conducting and documenting these services in the GuildCare platform, the pharmacist saves the case as ‘Conducted’ and provides a printed session summary to the patient.

The pharmacy will receive $10 for Session 1 if either the SMS reminders AND/OR the follow-up Session 2 phone call is selected. Otherwise, the pharmacy will receive $8 for the completion of Session 1 if no follow-up options are selected.

When the Session 1 case has been saved as ‘Conducted’, automatic claim submission via the GuildCare platform occurs.
Session 2 – conducted by pharmacy

Community Pharmacist Services

If the patient returns between Day 20-40 to collect their next Spiriva/Spiolto Respimat, an invitation will pop up for Session 2. Simply follow the GuildCare documentation tab while delivering the service;

Checking In

- Ask the patient if they have missed any doses of their Spiriva/Spiolto Respimat and select reasons where applicable
- Discuss any other questions the patient may have about their Spiriva/Spiolto Respimat
- Remind the patient when their next prescription is due
- Report any adverse events to TGA using methods outlined in Appendix A of this Protocol

SMS Reminders

GuildCare Programs

Patients must have consented to receiving these messages. GuildCare software automatically sends SMS reminders on behalf of your pharmacy (at no cost to you). Patients will receive up to 3 SMS reminders unless they opt-out prior by replying STOP to the SMS.

SMS 1: Day 3
Hi! Just a quick reminder that a full dose of Spiriva/Spiolto Respimat is ONCE daily, TWO puffs. XXXXXX Pharmacy. To stop SMS reply STOP

SMS 2: 5 days before prescription is due (Reminder to pick up prescription)
Hi from XXXXXXX Pharmacy. Your next Spiriva/Spiolto Respimat prescription is nearly due. We look forward to seeing you soon. To stop SMS reply STOP

SMS 3: Day 32
Before using a new Spiriva/Spiolto Respimat, remember to prepare the inhaler. Come speak to our pharmacist if you need help. XXXXX Pharmacy. To stop SMS reply STOP

Follow-up Phone Call – conducted by GuildCare Pharmacist

GuildCare Pharmacist Support Centre (PSC) phone calls

Patients must have consented to receiving a follow-up phone call. The follow-up phone call is conducted over the phone by a GuildCare Pharmacist on behalf of your pharmacy. Patients will receive the follow-up phone call if they have consented to receiving a phone call but have not received Session 2 in pharmacy by Day 40.

During the phone call:

- The patient is asked if they have missed any doses of their medication and the reasons why (if applicable).
- GuildCare Pharmacist reminds the patient that regular use of Spiriva/Spiolto Respimat can help them to breathe more easily, and help minimise the effects of the condition on their everyday life
- If patient has ceased Spiriva/Spiolto Respimat, they are asked what the reason was for stopping
- The patient is asked if they have any further questions, and the session is documented.

After conducting and documenting this service, the GuildCare Pharmacist will record the outcome of this phone call and provide feedback to the pharmacy where relevant. GuildCare pharmacists will also report any adverse events that are identified during the phone call directly to Boehringer Ingelheim.
Appendix A: How to report a problem with a medicine or medical device to the Therapeutic Goods Administration

Information for health professionals


The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing and is responsible for regulating medicines and medical devices. The work of the TGA is based on applying scientific and clinical expertise to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices. The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices so that the TGA can identify and respond to safety matters.

When to report

If a patient has experienced or you suspect they may be experiencing an adverse event relating to a medicine or medical device, report the adverse event to the TGA. Suspected adverse events should be reported the first time they occur, as well as any time they occur thereafter.

What to report

Please report any suspected adverse event that your patient(s) may be experiencing, in particular:

- serious reactions (e.g. resulting in hospitalisation)
- unexpected reactions (reactions not consistent with consumer medicine information or labelling)
- all suspected reactions to medicines recently introduced in Australia
- all suspected adverse events that may be caused by combinations of medicines (drug interactions)
- faults with medical devices resulting in an adverse event (keep the faulty equipment until you have contacted the TGA).

What to include in your report

In your report include (if applicable):

- basic details of the patient experiencing the adverse event – initials, date of birth, gender
- details of the adverse event or reaction – date it occurred, symptoms experienced (including duration), description of device fault resulting in adverse event, treatment required and outcome (if known)
- details of the medicine or device involved – name, description, dose, for a complementary medicine include AUST L number
- details of any other medicine(s) the patient experiencing the adverse event may be taking.

Report a medicine or medical device adverse event to the TGA

How to report

Report a suspected adverse event directly to the TGA using:

- GuildCare’s Adverse Events Recording module, sent electronically via a web service portal direct to the TGA

Alternatively:

**Medicines**

Phone: 1300 134 237 or 1800 044 114

Email: adr.reports@tga.gov.au

**Medical devices**

Phone: 1800 809 361

Email: iris@tga.gov.au