EZETROL®/VYTORIN®

(ezetimibe/ezetimibe + simvastatin)

Compliance GuildCare Program

PROTOCOL

This document provides information on conducting the EZETROL®/VYTORIN® Compliance Program using GuildCare software.

December 2013

Version 1.1

Table of Contents

Program sponsored by:

MSD

Merck Sharpe & Dohme (Australia) Pty Ltd
Level 1, 26 Talavera Rd, Macquarie Park NSW 2113, Australia

Program powered by:

guildcare

DIAB-1100567-0000 First issued November 2013

Executive Summary

Program Objective: to inform and support poorly compliant EZETROL® and VYTORIN® patients in achieving optimal long term treatment outcomes through better compliance.

Patient Qualification and Notification: Using dispense history, the GuildCare software will automatically detect patients who have an EZETROL®/VYTORIN® Meds*Index* score below 70 using dispense history. A pop-up notification will occur at the point of dispense.

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 expire and be removed.

Clinical Service: The clinical service is conducted with the patient over a single session in the pharmacy and must include **at least one** patient-consented follow-up service to be saved as "Conducted". The patient can choose to enrol and receive up to three SMS reminder messages by GuildCare software. Additionally, if the patient has not collected their next repeat prescription (following enrolment prescription) within 40 days, they can choose to receive Session #2 in the form of a follow-up phone call from a GuildCare pharmacist on behalf of the pharmacy. This session is documented in the GuildCare software. After Session #1 is saved as conducted in the GuildCare platform, the pharmacy receives payment of $7.50 for the session.

Summary of Sessions

Enrolment

1. Invite patient into program
2. Ensure the patient is **NOT** enrolled in the EazyStep program - tick to indicate if they are. (NB: Patients already enrolled in EazyStep are **NOT** eligible for this GuildCare EZETROL®/VYTORIN® Compliance Program)
3. Provide patient with 'Privacy Policy and Terms of Use' then indicate they have read and agreed
4. Provide patient with EZETROL® or VYTORIN® CMI and discuss potential adverse effects
5. Invite patient to receive either SMS reminders and/or follow-up session via phone call

Note: If patient does not consent to receive either SMS reminders and/or follow-up phone call, they cannot be enrolled in the program.

Session #1 *(conducted by Pharmacy)*

1. Ask the patient what they know about EZETROL®/VYTORIN® and the reason they've had it prescribed
2. Ask the patient when they last had their cholesterol levels checked. Record results if available
3. Discuss barriers to adherence and how to overcome these barriers
4. Discuss and set a daily dosing routine
5. Provide support materials, document session, provide printed session summary then save as Conducted

SMS Script Reminders

GuildCare software sends an SMS to remind patient their script is due to be dispensed. Continues for up to 3 SMS Reminders unless the patient opts out.

Session #2 *(conducted by GuildCare Pharmacist on behalf of the pharmacy)*

Session 2 content is delivered by a GuildCare Pharmacist via follow-up phone call to patient.

Program Information

This document describes the services of the EZETROL®/VYTORIN® Compliance Program as delivered by pharmacists. In this program the pharmacist conducts a clinical service with each participating patient using the GuildCare software. Use this protocol document for the detailed instructions on what to do when conducting the program.

Program Objective

The objective of this program is to inform and support poorly compliant EZETROL®/VYTORIN® patients in achieving optimal long term treatment outcomes.

Program Overview

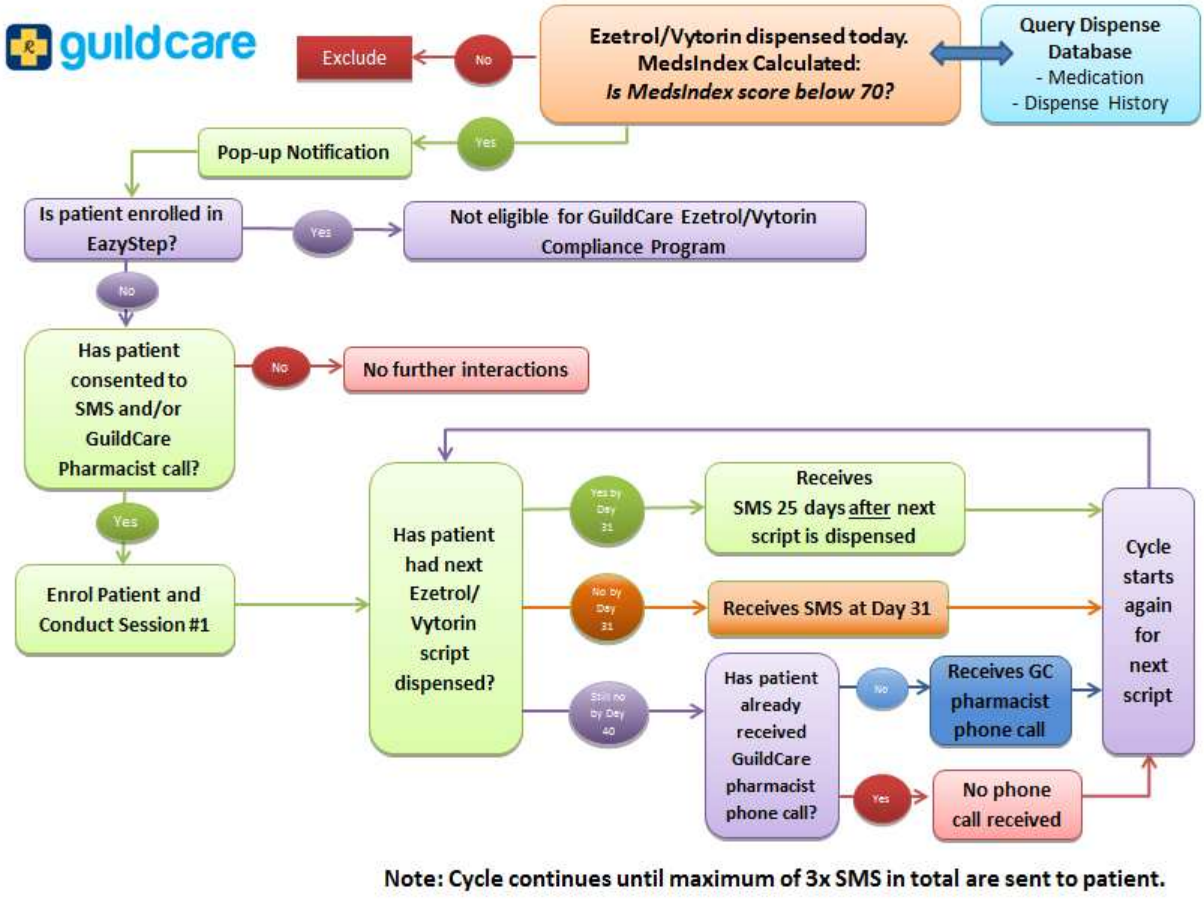

Figure 1: EZETROL®/VYTORIN® Compliance Program Session 1 overview

As part of delivering the EZETROL®/VYTORIN® Compliance 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.

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 dispense records at your pharmacy. It does not link with any other pharmacy. Patients cannot be added 'ad-hoc' into this program.

Patients qualify if they:

1. **have had EZETROL®/VYTORIN® dispensed in the past 12 months and**
2. **have a Meds*Index** score of less than 70**

Patients can only enrol in the program if the GuildCare software detects that they qualify.

***Meds*Index* score**
Definition: An indicator of patient medicines compliance. It is calculated from how much medicine the doctor intended the patient to take compared to the actual interval between the patient's dispense dates. i.e. Prescribed: EZETROL®/VYTORIN® (30 tablets) 1 dose daily:

Pack size 30 doses ÷ 1 dose daily = 30 days of medicine

Patient's actual interval between repeats = 45 days

30 ÷ 45 = 0.67 = 67% : Meds*Index* = 67

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. If the pharmacist ignores the notification it will stay valid for seven days then will be removed. Before enrolment, patient must also be provided with an EZETROL®/VYTORIN® Consumer Medicine Information leaflet (CMI) and given the chance to ask any questions about their medication. This is actioned by ticking the box to verify this document has been provided. See Clinical Services Information for more details.

Patient Consent and Enrolment

Upon notification consider whether the patient has had multiple prescriptions dispensed at other pharmacies. Approach each patient and discuss their EZETROL®/VYTORIN® use. 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. They must be provided with the product CMI and program 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.

Patient Decline

If the patient does not qualify or declines to participate at any time, the pharmacist sets the Status as 'Declined' in the GuildCare software.

Program Structure

The program is to be delivered in a single session in the pharmacy and must include at least one patient-consented follow-up service to be saved as "Conducted". The follow-up services are SMS reminders and/or one follow-up second session phone call from GuildCare on behalf of the pharmacy:

- **Session #1**: in person in the pharmacy; when qualifying script is dispensed
- **Session #2 phone call:** patient must consent; conducted by a GuildCare pharmacist over the phone if no repeat prescription has been collected by day 40.
- **SMS Script Reminders:** patient must consent; an SMS reminder is sent:
    - if next repeat has not yet been collected 25 days after the previous prescription was dispensed
      and/or;
    - if next repeat has not yet been collected 31 days after the previous prescription was dispensed

  This repeats as a cycle until up to 3 SMS Reminders are sent. See Program Overview for more information.

Clinical Service Information

The time spent between the pharmacist and the patient in each session is at the discretion of the pharmacist. SMS Reminders and Session #2 follow-up phone call are conducted by GuildCare on behalf of your pharmacy, and the patient must consent to at least one of these options to qualify for the program. As a guide, pharmacists may take up to ten minutes to complete Session #1.

Please read the 'EZETROL®/VYTORIN® Product Information for Pharmacists for more information about EZETROL®/VYTORIN® before delivering the services.

Enrolment

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

- Patient is:
    - Confirmed to NOT be already enrolled in the EazyStep program;
    - Informed they qualify for a free medicine support program sponsored by MSD;
    - Informed that the program is confidential but information about the service may be shared with their doctor;
    - 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"
    - Provided with an EZETROL® or VYTORIN® Consumer Medicines Information leaflet (CMI) and an explanation of the potential risks of the medicine as per the Medicines Australia Code of Conduct.

Session #1 – *conducted by pharmacy*

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

Your Medicine

- Discuss/Explain:
    - Current Meds*Index* score;
    - The meaning of the score in terms of '__days out of 10';

        - i.e. A Meds*Index* score of 60 equates to the patient taking the medicine 'only 6 days out of every 10 days'
    - Any additional information/counselling regarding the patient's medication.

Quality Use of Medicines

- Ask the patient:
    - What they know about EZETROL®/VYTORIN® and the reason they've had it prescribed
    - When the last time they had a blood test done for their cholesterol levels was
        - Document their total cholesterol level and/or LDL cholesterol level if known
    - What they feel holds them back from taking their EZETROL®/VYTORIN® every day?
- Discuss and record:
    - What the patient feels would help them to take EZETROL®/VYTORIN® more regularly
    - How they will fit taking EZETROL®/VYTORIN® into their daily routine, and help the patient to establish a good routine
- Remind the patient when their next script is due.

Pharmacist summary/recommendation

- Provide any personal comments
- Provide any recommendations for patient

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.

When the Session #1 case has been saved as conducted, automatic claim submission ($7.50) via the GuildCare platform occurs.

SMS Script Reminders

GuildCare software sends SMS reminders on behalf of your pharmacy reminding patients that their next EZETROL®/VYTORIN® script is nearly due to be dispensed. Patients must have consented to receiving these messages by providing their phone number, after reading the Privacy Policy and Terms of Use.

Option 1: Day 31 (Patient has not picked up prescription on time)
Hi from XXXXXX Pharmacy. Have you picked up your EZETROL/VYTORIN script? If you have any questions ask your doctor or pharmacist. To stop SMS reply STOP

Option 2: 5 days before next script is due (Reminder to pick up prescription)
Hi! Your next EZETROL/VYTORIN script is nearly due. We look forward to seeing you soon. XXXXXX Pharmacy. To stop SMS reply STOP

GuildCare will automatically detect if patient is using EZETROL® or VYTORIN® and send the appropriate drug brand name in the SMS. Either Option 1 or Option 2 will be sent to the patient depending on their situation to a maximum of 3 SMS Reminders unless the patient opts out. See Program Overview for more information.

Session #2 (Follow-up) – *conducted via phone call by GuildCare Pharmacist*

GuildCare Pharmacist services

This optional Session #2 follow up is conducted over the phone by a GuildCare Pharmacist on behalf of your pharmacy. The patient must have consented to this follow up session by providing their phone number. The patient will be eligible for the follow up phone call if no repeat prescription has been collected from 40 days after original script has been dispensed.

Your Medicine

- The patient is asked:
  - In the last week, how many days they have taken their EZETROL®/VYTORIN®
  - If the answer is less than 6 days, what they think has stopped them from taking their EZETROL®/VYTORIN® every day
- GuildCare Pharmacist discusses the patient's daily routine and addresses any issues identified
  - GuildCare Pharmacist explains to the patient that even though high levels of cholesterol do not make them feel unwell, it can cause problems if left untreated such as increasing their risk of having a heart attack or stroke and this is why it is important for the patient to take their EZETROL®/VYTORIN® regularly every day
- The patient is asked how the plan to fit taking their EZETROL®/VYTORIN® into their daily routine they discussed with one of the pharmacists in the pharmacy has worked for them; if it has not worked, GuildCare Pharmacist discusses with patient alternative strategies that may work better for them
- If patient has ceased EZETROL®/VYTORIN®, they are asked what the reason was for stopping EZETROL®/VYTORIN®
- The patient is asked if they have any further questions, and the session is documented.

After conducting and documenting these services, the GuildCare pharmacist will record the outcome of this session #2 and provide feedback to the pharmacy where relevant.

Appendix A: How to report a problem with a medicine or medical device to the Therapeutic Goods Administration

Information for health professionals

Source: http://www.tga.gov.au/hp/problem.htm

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).

How to report

Report a suspected adverse event directly to the TGA using:

- the TGA website - http://www.tga.gov.au/safety/problem.htm

In addition, for medicines you can report using the:

- 'Blue card' reply paid reporting form (download and further information are available on the TGA website)
- TGA's Adverse Medicine Events Line (1800 044 114).

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

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

or visit the TGA website