**Frequently Asked Questions**

**1. What is BlueStar® intended to do?**

Intended use

BlueStar is a Software as a Medical Device (SaMD) intended to be used by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. BlueStar is intended to assist patients in managing their diabetes with guidance from their providers. BlueStar has two versions – BlueStar and BlueStar Rx.

Indication for use

BlueStar® is indicated for use by healthcare providers (HCPs) and their patients – aged 18 years and older - who have type 1 or type 2 diabetes. BlueStar is intended to provide secure capture, storage, and transmission of glucose data as well as information to aid in diabetes self-management. BlueStar analyzes and reports glucose test results and supports medication adherence. In addition, BlueStar provides coaching messages (motivational, behavioral, and educational) based on real-time glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetesrelated healthcare information and provides educational information.

The following BlueStar insulin management features are for prescription use only:

* For bolus insulin users with type 1 or type 2 diabetes, BlueStar includes an insulin dose calculator\* to allow patients to use their prescribed regimen to calculate a dose of bolus insulin for a given amount of carbohydrates and/or glucose value.
* For basal insulin users with type 2 diabetes, BlueStar includes an Insulin Adjustment Program (IAP) which calculates appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a healthcare provider. The healthcare provider must activate the IAP and configure it with patient-specific parameters.
* For bolus insulin users with type 2 diabetes, the BlueStar IAP calculates appropriate dose adjustments of bolus insulin based on configuration of a healthcare provider. Qualified type 2 diabetes patients are those who are not achieving glycemic targets despite optimization of their basal insulin dose or their current bolus insulin regimen.
* For premixed insulin users with type 2 diabetes, the BlueStar IAP calculates appropriate dose adjustments of premixed insulin based on the configuration of a healthcare provider. Qualified type 2 diabetes patients are those who are not achieving glycemic targets and who do not take other types of insulin.

BlueStar is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment. This is the oldest of all Welldoc Product.

*\*Insulin Dose Calculator may also be referred to as Insulin Calculator*

1. **What functions are available from BlueStar?**

BlueStar, a web-based management portal, is the health care provider-facing component of the BlueStar app. The primary functions of BlueStar include the following:

* + Invite patients to use BlueStar
  + Access SMART Visit Report®
  + Review patient data, Meds, and Health Info
  + Communicate with patients via email, in-app message center, chat, or video calls
  + Monitor patient population for engagement and outcomes
  + Create and send patient surveys
  + Initiate Insulin Adjustment Program and monitor progress (Prescription only)

For full instructions on use of BlueStar, view the User Guides under **Help**.

1. **What patient data can I view?**

* + Blood glucose, medications, food, activity, sleep, and blood pressure data
  + Blood glucose and insulin summary graphs
  + Basal, Bolus, or Premixed insulin dose adjustment history (if in an Insulin Adjustment Program)

1. **How do I use the patient list?**

Within the management portal, the patient list displays information to quickly monitor for engagement and/or outcomes. This may allow for identification of patients who may need outreach from the health care team.

Task cards will appear at the top when there are actions to review and take. Only prescribing providers can dismiss these task cards.

1. **What is the SMART Visit Report and how can I access it?**

The SMART Visit Report provides a summary of patient data, clinical decision support, logbook, and/or food diary. It can be accessed from the management portal, or it can be sent by your patients from the BlueStar app.

From the management portal, click the **Report** tab within the patient’s record. The SMART Visit Report will display on the screen or you may download a PDF.

**IMPORTANT:** The SMART Visit Report is intended to supplement, not replace, medical expertise, research, judgment, or diabetes treatment provided by the health care providers. The report provides information that can be used to identify trends to help inform health care providers’ treatment decisions. Decisions regarding diagnoses or treatment of patients will be made solely by the health care providers.

1. **How do I invite my patient to use BlueStar (non-IAP only)?**

From the Home screen, select **New Patient**. Then enter the required patient data and follow the prompts to complete invitation.

The patient will receive an email invitation to download BlueStar and register. The patient record will indicate “Waiting for patient” with a gray upright flask icon until they are registered.

1. **What is an Insulin Adjustment Program for basal, bolus, or premixed insulin?**

The Insulin Adjustment Program for basal, bolus, or premixed insulin is for prescription use only. The basal program titrates basal insulin doses based on configuration by a prescribing health care provider within the BlueStar management portal. The program is only available for patients with type 2 diabetes who use basal insulin and do not take bolus insulin.

The bolus program titrates bolus insulin doses based on configuration by a prescribing health care provider within the BlueStar management portal. The program is only available for patients with type 2 diabetes who are inadequately managed on non-insulin therapies and their current dose of basal insulin.

The premixed program titrates premixed insulin doses based on configuration by a prescribing health care provider within the BlueStar management portal. The program is only available for patients with type 2 diabetes who are inadequately managed on noninsulin therapies and their current dose of basal or premixed insulin.

Please refer to the Insulin Management Features (Prescription Only) user guide under **Help** for detailed information about the Insulin Adjustment Program.

**8. How do I initiate an Insulin Adjustment Program for basal, bolus, or premixed insulin?**

Only prescribing health care providers may initiate an insulin adjustment program for a

new or existing patient.

1. From the Home screen, complete the following steps:

1. For New Patients: Select **New Patient**. Then enter the required patient data and indicate that the patient will be undergoing an Insulin Adjustment Program (basal, bolus, or premixed).
2. For Existing Patients: Find and open the patient’s record. From the Treatment tab, select **Start new program**.
3. Follow the onscreen prompts to set up the titration parameters. When set up is complete, your patient will receive an email invitation to download BlueStar and register.
4. The patient record will indicate “Waiting for patient” with a gray upright flask icon until they are registered.
5. **How do I monitor my patient’s Insulin Adjustment Program for basal, bolus, or premixed insulin?**

At a glance, you can view the patients’ Insulin Adjustment Program (IAP) status, glucose values and dosing regimen from the Home screen. Open the patient’s record to the **Treatment** tab. In the “Insulin Adjustment Program” section, view the patient’s basal/bolus/premixed insulin dose and fasting blood glucose history.

1. **What is the Insulin Calculator for bolus insulin?**

The Insulin Calculator for bolus insulin is for prescription use only. The Insulin

Calculator helps determine bolus insulin doses based on the prescribed regimen. Authorization by a prescribing health care provider is required via a fax request.

1. **Who is eligible for the Insulin Calculator for bolus insulin?**

To be eligible for the Insulin Calculator (Prescription only), patients must use a qualifying bolus insulin and insulin dosing regimen. Please refer to the Insulin

Management Features (Prescription Only) user guide under **Help** for detailed information about the Insulin Calculator.

1. **How do I authorize the Insulin Calculator for bolus insulin?**

If the patient would like to use the Insulin Calculator, a Prescription Request Form can be sent from the app to the provider containing the dosing information the patient entered into the app.

***Note:*** *Only prescribing health care providers can authorize the Insulin Calculator. Please refer to the Insulin Management Features (Prescription Only) user guide under* ***Help*** *for detailed information about the Insulin Calculator.*

1. **How do I revoke Insulin Calculator authorization?**

The Insulin Calculator (Prescription only) authorization is valid for 365 days after authorization. To remove access sooner, please call BlueStar Customer Care at 1-888611-4794 Monday – Friday, 8 AM – 6 PM (EST).

1. **Where can I find the User Guides?**

To locate the BlueStar User Guide and Insulin Management Features (Prescription only) user guide, select **Help** on the Home screen.

1. **How are the management portal user roles defined?**

There are four types of user roles in BlueStar: admins, prescribing health care provider, non-prescribing health care professional and EMR case manager.

When a new patient is added, all users associated with the clinic or account can view the patient’s record. Only prescribing health care providers can initiate the Insulin Adjustment Program.

To view your assigned role, look under your name on the top right of the screen.

1. **How can I add other management portal users to my clinic or account?**

Please work with your account representative to add new users. To add a new prescribing health care provider user, the health care provider’s NPI number is required.

1. **I forgot my password. How can I reset it?**

* 1. From the BlueStar login screen, select **Forgot Password**.
  2. Enter your username or email address.
  3. Choose how you want to get your temporary password:
     + Email
       1. Check your email for more information about resetting your password.
       2. Follow the instructions in the password reset email to reset password.
     + Text message (only available if your mobile phone number has been entered in

BlueStar for purposes of authenticating your account)

* + - 1. Check your mobile device for your temporary password.

1. **I forgot my username. How can I reset it?**

* 1. From the BlueStar login screen, select **Forgot Username**.
  2. Enter your email address.
  3. Choose how you want to get your username:
     + Email
     + Text message (only available if your mobile phone number has been entered in

BlueStar for purposes of authenticating your account)

* + - 1. Check your mobile device for your temporary password.

1. **Which browsers are compatible with the BlueStar Management Portal?**

To ensure security, it is recommended that desktop users keep their browser up-to-date and have anti-virus installed.

The default/preferred browser that will be supported for the management portal is Google Chrome™, Mozilla Firefox®, Microsoft Edge®, and Internet Explorer.

Devices that do not meet the above criteria are not compatible with BlueStar.

1. **How do I know when the management portal has been updated?**

You can find the latest information about BlueStar by looking at the software version number under **Help**.