Integrating Digital Therapy into the daily diabetes self-management and care for adults with diabetes
Welcome to BlueStar®:

**Indication for use**

BlueStar is indicated for use by health care providers and their adult patients — aged 21 years and older — who have diabetes. BlueStar is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. BlueStar analyzes and reports blood glucose test results and supports medication adherence. In addition, BlueStar provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional health care settings. The software also allows for entry of other diabetes-related health care information and provides educational information.

BlueStar is not intended to replace the care provided by a licensed health care provider, including prescriptions, diagnosis, or treatment.

**Contraindications**

BlueStar is not indicated for people with gestational diabetes or who use an insulin pump. For more information, call Customer Care at 1-888-611-4794.

Welcome to BlueStarRx®:

**Indication for use**

BlueStar Rx is indicated for use by health care providers and their adult patients — aged 21 years and older — who have diabetes. BlueStar Rx is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. BlueStar Rx analyzes and reports blood glucose test results and supports medication adherence. In addition, BlueStar Rx provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional health care settings. The software also allows for entry of other diabetes-related health care information and provides educational information. BlueStar Rx includes an insulin dose calculator to allow patients to use their prescribed regimen to calculate a dose of insulin for a given amount of carbohydrates and/or blood glucose value.

BlueStar Rx is not intended to replace the care provided by a licensed health care provider, including prescriptions, diagnosis, or treatment.

Federal law restricts this device (BlueStar Rx) to sale by, or on the order of, a licensed health care provider.

**Contraindications**

BlueStar Rx is not indicated for people with gestational diabetes or who use an insulin pump. For more information, call Customer Care at 1-888-611-4794.

Customer Care: Ready to Answer Your Questions

Need help using BlueStar or BlueStarRx? Call us at 1-888-611-4794.
Available Monday – Friday 8:00 am – 6:00 pm (ET).
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BlueStar Overview

BlueStar was designed by physicians and diabetes educators to help patients and their healthcare team:

- Improve self-management of diabetes
- Support medication adherence
- Inform clinical treatment decisions between health care provider and patients

BlueStar provides real-time guidance to patients via a HIPAA compliant, mobile, cloud-based platform. BlueStar delivers personalized, contextualized content to a patient that aligns with the American Diabetes Association (ADA) guidelines and Diabetes Self –Management Education and Support (DSMES) national standards. It is driven from the patient’s treatment plan to help improve patient outcomes. BlueStar meets the DSMES Standard: *Ongoing Support*. BlueStar is cleared and regulated by the FDA.

BlueStar Implementation Steps

Patient Identification

- Eligibility: Product Intended Use and technology assessment
- Project defined criteria

Enrollment

- Outreach and recruitment strategy: Informing identified patients of availability of BlueStar and providing with an Access Code
- Submitting a Service Request Form (prescription required for using insulin calculator) with patient and provider information or enrollment file.
- Determining the destination/recipient(s) of the SMART Visit Report

Onboarding

- App activation and registration
- Guided prompts and videos help patient get started
- BlueStar Journey: Accepting Weekly Challenge
- Initial engagement call (depending on protocol)

Customization

- Med set-up (creating med list or syncing from pharmacy or patient portal)
- Daily schedule adjusted to match users daily routine
- Health Info entered or synced from laboratory (Quest or Lab Corp) or patient portal; add SMART Visit Report recipients and scheduling desired reports

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V5.2 Online Version
• Glucose monitors, activity trackers synced, daily schedule adjusted as needed to match user’s
daily routine, preferred language (English or Spanish) selected
• Daily use plan

Patient Engagement (BlueStar Journey)

• Daily BlueStar use: Based on the Weekly Challenge or per self-management plan, enter or sync
  Blood Glucose (BG), Blood Pressure (BP), weight; add notes to add context to the entries, record
  meds, insulin, food, exercise and sleep. Review guidance provided and access education
  resources of most relevance and interest.
• Episodic BlueStar activities: Review logbook and trends (graphs), prior to health care team visit
  or as needed to identify and resolve glucose or BP excursion patterns, send a SMART Visit
  Report prior to a health care team visit or virtual touchpoint, update Health Info and Meds after
  the health care team touchpoint

Team Engagement

• Integration of BlueStar and other digital health tools into clinical workflow, practice and services
• Use of SMART Visit Report (summarized Patient-Generated Health Data) at visit and between
  visits at virtual touchpoints to partner with the patient to optimize care plan
• Use of population level data to support practice and quality improvement initiatives

Module 1: Patient Identification

Indications for BlueStar

The WellDoc BlueStar® System is intended to provide person-centered, self-management support for
individuals 21 years of age and older, for diabetes and its co-morbidities (especially hypertension and
weight management). It is intended to provide automated, dynamic educational, clinical and behavioral
messaging support and feedback that is created by combining patient generated health data (PGHD)
with evidence-based guidelines. Additionally, PGHD is analyzed and compared against professional
organization guidelines to provide clinical decision support to healthcare providers. The Welldoc
BlueStar® System is intended to enhance self-management and may lower A1C. The Welldoc BlueStar®
System is not intended to replace the care provided by a licensed healthcare professional, including
prescriptions, diagnosis, or treatment.

BlueStar is not indicated for people who:

  o Have gestational diabetes
  o Use an insulin pump (including V-Go)
Technology Assessment

Assess use of technology in daily life (computer, mobile device, use of apps) to determine eligibility for product as well as to determine the device to train (iPad/phone, Android phone, Web portal)

- Do you use a Smartphone, tablet or a computer?
  - If the response is, “what is a smartphone?”, and you have to say more than an iPhone or an Android that you can put apps on, this is likely not a good candidate.
- Do you use the internet on your computer in your home at least 2 times a week?
  - This shows if they understand how to use the computer and will use the internet (some people have a computer and no internet.)
  - “In your home” is very important because some people may use a computer at work, but do not feel comfortable putting private health information in a work computer.
- Do you have apps on your phone?
  - Can also say, “do you use Facebook?”; On the phone or on the computer?
    - If they can use Facebook on the phone, they are more than savvy enough to use the product.

Program criteria and recruitment strategy

- Determine other criteria for patient identification and recruitment strategy based on stakeholders’ objectives

Module 2: Enrollment

Determine plan for informing identified patients of availability of BlueStar and provide Access Codes. Both BlueStar and BlueStar Rx are available. Individuals begin on BlueStar. When entering meal-time insulin, users are given an option within BlueStar to upgrade to the BlueStar Rx version. The BlueStar Rx version is required in order for the user to access the Insulin Calculator function. To prescribe BlueStar, the provider must complete the BlueStar Prescription Request Form and fax to BlueStar Customer Care. This form can be generated automatically within BlueStar upon the patient’s request. BlueStar is the first Digital Therapeutic acknowledged by the American Diabetes Association as a new category of treatment. It can be reimbursed via a unique NDC/NHRIC Code 89129-0100-01 or by direct billing.
Module 3: Onboarding

Introduce patient to BlueStar:

- **To the patient:** “BlueStar is an app designed to support people with diabetes as they live their life and manage diabetes. BlueStar makes it easy to share information with the health care team.”
- **Background information**
  - First in class – Digital Therapeutic (clinically validated app)
  - Developed and tested by diabetes educators, doctors, and patients
  - Recommended (or prescribed) by your healthcare team

Onboarding Steps

The account can be set up using the web portal or the mobile device. All information will be available on both the mobile and the web portal when the phone is connected to cell service.

1. Enter Access Code
2. Acknowledge Terms of Use (software) & Patient Authorization (personal health information sharing)
3. Enter personal information and e-mail address the patient wishes to associate with BlueStar
4. Respond to medication question
5. Create User Name and Password
6. Click *Create Account* (In mobile, the user is also prompted to create a PIN to protect private Health Information and to give permission to send notifications)
7. The patient will be routed to the BlueStar web portal or to the app if initiating the account on their mobile device.
   - The user is then invited to begin their BlueStar journey by accepting a Weekly Challenge. BlueStar will guide the user’s experience through smart prompts regarding tracking various data at key times.
   - As the user engages with a particular BlueStar feature for the first time, they will be guided by integrated instructions and invited to watch a series of short (< 1 minute duration) optional videos on the following topics (these videos are available in the Help section for future review):
     - How to add a medication
     - How to complete your medication list
     - Setting up your insulin (if indicate you take insulin)
     - How to enter sliding scale insulin (if indicate insulin is dosed via sliding scale)
• How to enter insulin-to-carb ratio (if indicate insulin is dosed via insulin-to-carbohydrate ratio)
• Learn about SMART Visit Reports

Note: If using BlueStar on the web portal, suggest the patient create a bookmark for the web address (www.bluestardiabetes.com)

Download Error Message (Authentication Failed)
There are 2 reasons the message may be sent:
1. An incorrect user name and/or password was used when completing the final steps of BlueStar download or a user name or password has been changed.
2. The user is using the mobile application on two mobile devices. If this is the case: Select OK to the message and enter the username and password to log in.

In these scenarios a patient will receive the following message:
You have either changed your user name or password or you are using BlueStar on a different phone or tablet. For security reasons, you will be required to login with your user name and password.

Common Registration Questions
I can’t remember my Apple ID or Google Play account name
First you must find out your Apple ID or Google Play account name by opening up Google Play or the App Store, and clicking under registration details. There should be a spot where you Apple ID/Google Play account info is listed. There is also a button to reset your password. You will need your ID and the password to download the application.
To rest your Apple ID or password,
1. Go to My Apple ID and select Reset your password.
2. Enter your Apple ID, then click Next. If you don’t remember your Apple ID email address, choose Forgot your Apple ID, and follow the prompts
If the patient cannot figure it out, register the patient via the internet and once they figure the username/password out, they can obtain the mobile app.

I don’t have or can’t remember my e-mail address
If the patient does not have an email address that they regularly use, they are most likely not a good candidate. However, if they would like to proceed with registration anyway, a new email account can be created at gmail.com.

The app is asking for me to give permission to send notifications? Should I? What is this? Push notifications are used in the product to alert you of times to recheck your BGs, enter your weight or BP, take your medications, and other reminders you may set. Please be sure to say ‘YES’ or accept this notification as it is important to help you manage your diabetes within the application.
I can’t see the application when I search for it… what do I do?

1. First, let’s check your wifi connection. Are you connected to data (see a 3G or 4G sign at the top of the screen) or wifi? Wifi typically looks like a dot with semi circles above it and flashes in and out. You can also check for your wifi connection under the settings menu. If your wifi is not connected or you do not have service, you will not be able to search for apps.

2. Wifi is working – Ok, now can you pull the search back up and clear everything out of the search menu. Let’s try retyping BlueStar Diabetes into the search bar. Remember BlueStar is one word (spell the entire thing out… people commonly spell diabetes wrong).

3. If phone still doesn’t work, that’s ok. Let’s pull up the internet on your phone. We can get your registered on the web and then send a link to your phone to help you download it. Do you know where the internet icon is on your phone? If you are using an iPhone, it may also be labeled Safari. Please open the internet, and type www.bluestardiabetes.com.

4. Continue the web registration as listed above. After registration, send the user to the help menu and look on the left-hand side. There will be an option to send link via SMS to download on the phone. Ask the user to click their phone type (either Android or iPhone), and enter their mobile phone number. This will send them a text message to download the application. They must click the link in the message to download the application. Since you have already registered them, they can simply log in with their credentials once the application has completed downloading.

I’m not comfortable with the Patient Authorization section of registration. We regret to inform you that you cannot use the product unless you agree to the terms in the patient authorization. This is a standard usage agreement.

I don’t check my blood glucose. Why should I use BlueStar? BlueStar has lots of additional features such as the food diary for tracking your meals and the Restaurant Helper, where you can find restaurants in your area that have food items within a certain carb range. BlueStar also allows you to track your blood pressure, weight, exercise, sleep and how you are feeling with notes. You can also add your medications and set up a medication reminder to help manage your diabetes. BlueStar also allows you to share your information with your health care team.

I write everything in a logbook already. What is the added benefit of BlueStar? BlueStar allows you to record all of your information and provides real time coaching and feedback to help you understand your results. BlueStar also lets you send a report to your health care provider so together you can see how you are doing and make any necessary changes in your care plan. You can record your medications, set medication reminders, and even add notes on how you are feeling along with data you are tracking. BlueStar also has additional helpful features such as BlueStar Diabetes University, meal plans, recipes, videos, articles and a Restaurant Helper.
Onboarding via Smartphone

Downloading BlueStar Diabetes App on Apple Products

To get started, make sure the apple product is up to date (Version 9.0 or higher). To check, click the settings button (small gray wheel icon).

Scroll down to the General option, click and look at Software Updates. If an update is required, there will be a number next to software update. To update, click on the software update button followed by the download button. Once updated, BlueStar can be downloaded BlueStar.

To begin, click the blue App Store button.

Once in the App Store, click the magnifying glass in the bottom right hand corner that says “Search”. At the top of the screen, type BlueStar in the search box. Please be aware, BlueStar is one word. Click search. The first item that should appear in the list is the BlueStar Diabetes application. Click on the icon and click download.

Once complete, you are now ready to register BlueStar on the mobile phone. If you originally registered on your computer, use the login information set up previously. You may also send a link from the computer to the mobile phone for downloading.

Downloading BlueStar Diabetes App on Android Products

To begin, click the white Play Store button.
Once in the Google Play Store, click the magnifying glass in the top right corner. At the top of the screen, type BlueStar Diabetes in the search box. Note: BlueStar is one word. Click search. The first item that appears in the list is the BlueStar Diabetes application. Click on the icon and click download.

Once the download is complete, you are now ready to register BlueStar on the mobile phone.

If you originally registered on your computer, use the login information set up previously. You may also send a link from your computer to your mobile phone for downloading by going to the HELP page and clicking the link to send a SMS message to your phone.

Module 4: Customizing BlueStar

BlueStar is customized for the user by adding Medications, completing Health Information, adjusting schedule as needed in Settings, syncing with monitors, apps and devices the patient uses, and setting up SMART Visit Report recipients and scheduling when to send reports to the health care team.

Customizing BlueStar – Medications

For guidance in navigating the Medications Section, refer to the User Guide:
- Pages 9-10
- Upon registration, the user is prompted to enter their medications.
- If the medication profile includes a bolus short-acting insulin that requires calculation, a calculator is available by prescription. Refer to User Guide Page 20.

When the user is adding a medication for the first time, they will be directed to 2 videos “Why setting up your meds is important: and “How to Add Your medications” (demonstrates how to search for a med, then based on selection, user will be prompted with further questions)

Alternatively, the user can go to Setting and sync to their pharmacy or patient portal to have their medications automatically imported into BlueStar.

If on Short acting insulin:

User selects when they take insulin (with meals, at bedtime or as needed)
User is then prompted to answer “How do you take insulin? (Fixed amount, sliding scale (SS), correction factor (CF), Insulin to Carb Ratio (ICR), Fixed and SS, fixed and CF, ICR and SS, ICR and CF) (descriptions are available) User can select different dosing types for different meals

If selecting “As Needed” with Short Acting, can only select Correction Factor or Sliding Scale

**If on Long acting insulin or non-insulin medication:**

The user is prompted to answer, “How many times is it taken?”

Based on answer, the user is prompted to select frequency

The user is then prompted to “Tell us about your schedule” ➔ The user can adjust schedule and set reminders

**Creating Med list, scheduling meds, setting med reminders, logging meds**

- Selecting *Medications* tab from the menu allows the user to make a list of their meds, schedule reminders, and record meds
- There are 3 categories of medications than can be ordered: orals, non-insulin injectables, and insulin. If patients are having problems adding medications, provide guidance based on your scope of practice. Since insulin is a high risk drug, any support regarding insulin must be provided by a licensed individual.
- If items of concern regarding the patient’s treatment routine are uncovered when entering medications, e.g., the medication list provided by the prescribing provider includes a much smaller dose of rapid insulin at mealtimes than the patient reports taking, contact the prescribing provider to notify them of the discrepancy. Use best professional judgment in determining if a particular situation is of significant import to communicate to the provider.
  - **Medication List** – enter current medications; update/edit list as medications change over time (this must be done first before meds can be scheduled or logged); alternatively sync meds from your pharmacy (CVS, Rite Aid, Walgreens, Duane Reade) or patient portal
  - **Medication Reminder** – schedule medications by morning/noon/evening/bedtime; set reminders to take medications
  - **Record Meds** – track the medications taken by the meal, the time of day, or the entire day

From the *Medication List* tab, select *Add*.

- When searching for meds, enter the first 3-4 letters of the medication name; select the medication from the list that appears (no free text); if a medication is not available in the database, inform BlueStar Customer Care.
- All information needs to be completed before selecting “Save”. After saving, the user is prompted to schedule the med and set a reminder
In the interest of time available for onboarding, enter meds in the following priority order:

- Diabetes medications
- Hypertension & Hyperlipidemia medications
- All other

**Adding As Needed Medications**

Adding *As Needed* meds to the medication list, allows patient to log *As Needed* meds in their Daily Med Log by clicking the + at the end of the meds for a particular time of day then searching for the *As Needed* med, checking it, and adding the dose.

**To edit the Medication List,**

- Click edit pencil icon next to the medication name
- Change or click the arrow to change the strength of the med, the dose, or how often it is taken
- Click the delete button to remove the medication from the medication list

It is possible to print the medication list from the web portal. This could be helpful for patients only using the web portal who wish to have a current list of meds to carry with them for reference or sharing with other health care providers. Patients will have a complete list of their medications on their mobile device.

**Record medications day by day**

- Record medication for
  - Entire day with one check
  - Time of Day (Morning, Noon, Evening, Bedtime)
  - Log one medication at a time by checking the individual med
  - Log As Needed meds in Record Meds by clicking the + at the end of the meds list for a particular time of day/meal then searching for the med form the meds list, checking it and adding the dose

**Insulin dose calculator (Available via Rx-only)**

The insulin calculator uses the regimen entered by the User in their medication list to calculate the correct dose of insulin to take based on their carbohydrate and/or blood glucose value.

This feature is available through upgrade from BlueStar to the BlueStarRx product. Within the BlueStar application, the user requests access to the Rx functionality, including the Insulin Calculator function. The user inputs their prescribing healthcare provider information, which then triggers a prescription form requesting access to BlueStarRx. With proper prescription authorization, the user is upgraded to the BlueStarRx product, where the BlueStarRx calculator is enabled. When the user records a type of
insulin that has a flexible dosing regimen, a link to the insulin calculator is made available to determine the dose based on their insulin regimen. Examples of a flexible regimen include:

- An insulin-to carbohydrate ratio (insulin doses based on the number of carbohydrates being eaten)
- Correction factor (insulin doses based on blood glucose value)
- Sliding scale (insulin doses based on blood glucose value)
- Any combination of these regimens

For guidance in insulin calculation, refer to the User Guide:
- Page 21

Customizing BlueStar – Health Information (Health Info)
The user will receive paced prompts to enter/update their Health Info.

For guidance in navigating the Health Information Section, refer to the User Guide:
- Pages 27

Within Health Info there are 5 categories: The more information that can be completed the better.
SMART Visit Report – This screen enables the patient to enter SMART Visit Report recipients with fax number and e-mail of recipient and to then schedule and send SMART Visit reports (Summary Report, Summary Report & Log, Full Report and/or 7-Day Food Diary) to selected recipients including sending to themselves. The health care team should communicate to the patient which report(s) should be sent and the timing for sending reports.
Clinical Results – Diabetes related clinical results

Guide the patient to enter numbers and dates for current lab results and blood pressure check. Alternatively, the patient can choose to import data from Lab Corp, Quest Diagnostics or their patient
portal through Human API by selecting this option from the Health Information screen and logging in with their account credentials.

The legend indicates if In Range, Overdue, Out of Range or Missing based on ADA Clinical Practice Guidelines/Standards of Care.

Click on any of the clinical results hyperlinks (web) or arrow > (mobile) to learn more about each of these measures and the recommended targets and to check historical entries.

**Preventive Health** – Important exams, vaccines, and DSMES & MNT

Click on any of these hyperlinks (web) or arrow > (mobile) to learn more about these important health checks and how often they should be performed.

Guide the patient in choosing the date for each exam or vaccination completed. Remind the patient to update the list whenever they have a new vaccine or exam to record.

**Medical History** - Diabetes related conditions only

If patients are not sure of the answer to some of these questions, encourage the patient to discuss it with their healthcare provider at their next visit.

Remind patients to update their Medical History after each provider visit as relevant.

**Care Process Note:**

- Patient can click on hyperlink (web) or arrow > (mobile) to learn more about each condition, clinical result, and preventive health check
- Remind the patient to update the information each time they have new results and to ask for a copy of their current lab results at each visit. Alternatively, advise the patient to access their Patient Portal if their provider uses an electronic health record to get a copy of their most recent lab results. This will facilitate the provider meeting required metrics for Meaningful Use and Patient Engagement. Alternatively, data can be imported from their Patient Portal or LabCorp or Quest Diagnostics.
- Advise patient to review the BlueStar U Skill Builder, Health Champion lessons, the ABCs of Diabetes articles and Avoiding Complications video series.

**Lifestyle** – Weight & Height (calculates BMI) and tobacco usage (significant for Meaningful Use)

Guide patients in adding their current weight and height (in feet/inches) and choose date; the BMI is calculated automatically. If patients have synced with other apps or devices that include this information, the data will indicate it is from the app/device.
Guide patients to click Tobacco Usage to enter smoking history.

**Customizing BlueStar – Settings**

For guidance in adjusting settings refer to the User Guide:
- Pages 12-17

**Configurable settings:**

**My Daily Schedule** – The default daily schedule can be customized to better meet the patient’s daily routine (for instance, a shift worker). Patient will also receive prompts to take meds based on their daily schedule.

**Default Schedule Times**

- Breakfast (6-9 AM)
- Lunch: (11 AM – 2 PM)
- Dinner: (5 – 8 PM)
- Bedtime: (9 PM – 12 AM)

The patient can make changes in these times by clicking the Edit Pencil Button.

**My Meters** – Sync to OneTouch Verio Flex meter if applicable

**My Apps and Devices** – The patient has the option to connect to the following apps and devices to connect to track food (Samsung Health only), activity, sleep, height, weight. The user can only connect with 1 device/app at a time. The user will need to login with their device credentials.

- **Apple Health** – BG, Blood Pressure, Sleep, Exercise, Steps, and Weight
- **Samsung Health** (Samsung device users) – Food, Sleep, Steps, Exercise, Weight
- **FitBit** – Sleep, Steps, Exercise, Weight
- **Garmin** – Sleep, Steps, Exercise, Weight
- **JawBone** – Sleep, Steps, Exercise, Weight
- **MisFit** – Sleep, Steps, Exercise

**Note:** If the user chooses to connect to another device/app, the user will need to disconnect from the current device/app in order to do so.

Only 1 BlueStar profile can be associated with a given activity tracking account at a time (e.g. only 1 BlueStar user can be associated with 1 FitBit device)
Data synced will display in both logbook and SMART Visit Report. The weight will display in LifeStyle and be used to calculate BMI. Weight will also display in the SMART Visit Report.

**My Preferences** – The user can customize the following:

- Email Reminder for Messages – subscribe or unsubscribe
- A1C Target – set to less than 7% or 8%
- Blood Pressure Target – set to less than 130/80 mm Hg, 140/90 mm/Hg, or 150/90 mmHg
- Language: English or Spanish

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**Care Process Notes:**

*Patient’s schedules can vary. Additional support may be needed to customize the schedule based on the patient’s usual routine.*

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For guidance on Choosing Preferences and Syncing to meter or activity trackers, refer to the User Guide:

- Pages 12-17

**Module 5: Patient Engagement: Daily & Episodic Use**

**Home Page**

The BlueStar **home page** displays important information to help the patient in managing their diabetes and to build their diabetes knowledge.

- A graph visualization of patient’s recent BG entries will be displayed as the user progressively engages with BlueStar.
- When a pattern is detected in the patient’s data, a pattern message will be presented on the home page.
- A Weekly Report with Insights is presented weekly and the user is invited to accept the next Weekly Challenge to continue their BlueStar journey.
- BlueStar U – the user is invited to begin or to continue available diabetes education courses and lessons.
- Motivational Message – regarding general health and well-being.
- Short, 2-5 minutes educational videos are designed to build knowledge about diabetes in short clips. Each is available for 2 log-ins (one per day) before it is replaced by a new one. The entire library of videos are available in the Resource tab.
- Recipes are suggested based on the time of day (Breakfast, lunch, dinner).
- Restaurant Helper – identifies nearby restaurants and identifies available menu items within the selected carbohydrate range.
The main menu (3 bars at the top left-hand side of the home screen) allows the patient to return to Home, view Logbook, access and record Medications, enter Health Info, access Messages, locate Resources, adjust Settings, and find Help.

From the Home Screen, the blue + sign is a quick way to enter Medication BG, Food, Insulin, Activity, Blood Pressure, Weight and Sleep.

Making Entries (Real Time and Historical)

For guidance on Making Entries, Viewing Logbook & Getting Feedback refer to User Guide:

- Pages 17-26

Click on the + (New Entry) on either the web portal home page or mobile application. A New Entry screen will open. By default the date and time match the date and time on the patient’s device. Change the date and time and entry type as needed if making an historical entry. Users may also add notes to provide context to their entries (free text or from drop-down lists regarding Food, Schedule, Mood, Activity, or Meds)

Track Meds - Based on time of day (morning, midday, evening, bedtime) the patient will receive prompt “Did you take your meds?” based on daily schedule.

Individuals who have a prescription to use the BlueStar Rx product, have access to the Insulin Calculator within the Medications section. When recording insulin with a flexible dosing regimen (insulin-to-carbohydrate ratio, correction factor, sliding scale, or any combination of these regimens) the Insulin Calculator can be used to calculate the correct dose of insulin to take based on recorded carbs and/or blood glucose value.

Enter or sync BG - If the user has synced their OneTouch VerioFlex blood glucose meter to BlueStar, they can choose to sync their Blood Glucose reading(s) from their meter

Track Food - Patients can set a target Carb Range, select “Add a Meal” and search for foods using the food database, or take a picture of their food and use the food recognition API to select their food and amount, add just a photo of their food, or “Just add carbs”. Additionally, patients can access recently recorded meals or scan a barcode of an item they would like added to their meal. Lastly, patients can record their water intake at the bottom of the food diary page. When a patient selects a food and the portion size they are planning to eat, the carb amount of the selected food is placed on a gauge in the Food Diary. The gauge is a representation of the carbohydrate content of their meal compared to their Carb Target Range. If the patient does not set a Carb Target Range, the gauge will not contain a marker. Once completed, the patient can then confirm the total carbs and record as a New Entry in BlueStar.
Track **Activity** – Type (Bicycling, dancing/aerobics, gardening/lawn, hiking, home activities, running, skiing/skating, strength training, swimming, walking, Yoga/Pilates, other) & Duration or alternatively sync to activity trackers.

Track **Blood Pressure** – Enter systolic and diastolic blood pressure readings, pulse, and any relevant notes

Track **Weight** – Enter current weight, set goal weight and/or tracking reminders

Track **Sleep** – Bed Time and Wake Time or sync to activity trackers

---

**Care Process Note:**

Emphasize the importance of adding notes about the entries made. Notes provide context around the entries, are provided with the data in the SMART Visit Report facilitating problem solving for the patient and the provider.

An alternative to logging Food, is to select Food Notes and add a note indicating if the meal was smaller than usual, the normal amount, more than usual or skipped.

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**Real-time Guidance**
BlueStar provides coaching messages for entries that are within 120 minutes of the time the blood glucose or blood pressure was checked and entered or within 30 minutes if the blood glucose is less than 70 mg/dL. For example, if the BG was tested at 8:00 am and the patient is entering a non-hypo BG at 9:30 am clock time but is recording it as 8:00 am reading, the patient will still receive a message.

**Weekly Summary & Insights**
BlueStar provides a summary of entries for the past week on a weekly basis in the BlueStar Message center. The user can choose to select “Read More” to view additional insights regarding the various entries made.

**Logbook**
The Logbook displays all the users’ entries. The Logbook is customized based on whether the user takes insulin. The user selects the date ranges to set the date range the user desires to view.

The user can add, change, or delete entries (manually entered blood glucose, food, medication, activity, sleep, blood pressure, and weight) from the Logbook. Mealtime insulin doses can only be deleted from Record Medications.
Care Process Notes:

Help the patient understand the benefit of the paired checks to learn about their overall glucose management (bedtime/fasting pair) and the direct effect of their meals (paired meal checks).

To view or edit the meds or the notes logged, click on the med or notes icon in the logbook. The Edit Entry screen will appear. From this screen, click on Meds or Notes to view (or edit) meds or notes logged.

BG Targets are displayed at the top of the log or graph (web portal) based on personalized A1C target of < 7.0% or < 8.0%:

<table>
<thead>
<tr>
<th>Target Range</th>
<th>A1C Target &lt; 7.0%</th>
<th>A1C Target &lt; 8.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting</td>
<td>80 – 130 mg/dL</td>
<td>90 – 150 mg/dL</td>
</tr>
<tr>
<td>Before Meals</td>
<td>80 – 130 mg/dL</td>
<td>90 – 150 mg/dL</td>
</tr>
<tr>
<td>After Meals</td>
<td>80 – 179 mg/dL</td>
<td>90 – 200 mg/dL</td>
</tr>
<tr>
<td>Bedtime</td>
<td>90 – 150 mg/dL</td>
<td>100 – 180 mg/dL</td>
</tr>
</tbody>
</table>

Care Process Notes:

Orient the patient to the graphs during the training session so the patient can maximally benefit from the graphs on their own between visits.

What to teach: Explain the shaded area is the optimal target range for BG based on their personalized A1C goal. Patients can readily understand the concept of “staying between the lines”.

Be sure patients understand that it is expected that at least some of their BG readings will fall outside the target range. BG results are not a grade or a judgment but information that when translated into action becomes a valuable problem solving tool, particularly if the patient entered notes at the time of the BG entry so the context of the reading is understood. It often helps to use the word, “check” vs. “test”.

Messages

For guidance on navigating to Messages, refer to User Guide:

- Pages 24-25

The Message Center provides messages regarding:

- Pattern Reports
- Weekly Reports and Insights
- SMART Visit Report
Restaurant Helper
This Restaurant Helper enables the patients to find selections from the menus at local restaurants that fit within a range of carbohydrates that the patient specifies. Restaurants are identified based on the patients’ location (mobile). The patient can also search restaurants by zip code, allowing a patient to investigate restaurant and menu choices ahead of time to aid in planning.

Care Process Notes:
The diabetes educator can assist the patient in identifying healthy choices at local restaurants by using the Restaurant Helper. In addition to assisting the patient in selecting menu choices within their carbohydrate range, the diabetes educator can provide further guidance to the patient on healthy restaurant menu selections based on the fat, sodium, and calorie content of the food selections.

Resources
The Resource section includes:

Ask An Educator
This gives the user the opportunity to submit general diabetes questions to WellDoc’s team of diabetes educators and receive answers through the BlueStar Message Center. This is not intended for medical or emergency questions which should instead be directed to the patient’s own care team or through 911 accordingly. Questions and answers may be displayed for other users to see, however the identity of the user submitting the question will remain private as “Fellow User”. Users can search all the posted questions and answers by a topic or keyword, or select from diabetes self-management education categories.

BlueStar U
The AADE7 Self-care Behavior Curriculum is digitally embedded in BlueStar and delivered in 8 topics, 21 courses, and 91 lessons over a 12 week journey customized to the users therapy type, duration of diabetes and areas of interest. The user is able to view their progress through BlueStar U on their home screen. The user’s progress is displayed on the SMART Visit Report for the health care team. The user is able to review any courses and lessons previously completed.

Healthy Recipes
• View breakfast, lunch, dinner, and snack/dessert recipes along with nutrition facts.
• View healthy meal plans for varying calorie levels.

Diabetes Videos
Includes videos in the following categories:
• About Diabetes
• Managing Your Diabetes
• Healthy Eating
• Carbohydrate Counting
• Avoiding Complications
• Taking Medications
• Monitoring Blood Glucose
• Being Active
• Coping
• Solving Problems

Living with Diabetes
Includes articles in the following categories:

• The ABCs of Diabetes
• Carbohydrates
• Eating Well
• Eating Out
• Exercise
• Stay Healthy
• General Nutrition Information
• General

Diabetes Education Services
Learn when to receive diabetes self-management education and a link to the American Association of Diabetes Educators (AADE) web site to search for approved or recognized diabetes education services locally.

For guidance on navigating the Resources content, refer to User Guide:

○ Pages 32-33

Care Process Notes:
Guide the patient in referencing the various resources available that are most relevant to their current learning needs and behavioral goals.
Preparing for Healthcare Team Visit – Sending SMART Visit Report

The SMART Visit Report is a summary of the data the patient has entered into BlueStar over the past 30 days. It is sent to the healthcare provider as requested or prior to the next visit. The SMART Visit Report can also be sent to other recipients that the user chooses. There are 3 versions of the SMART Visit report available in addition to a 7-Day Food Record. The health care team should communicate to their patient using BlueStar which report(s) they prefer to have sent to them and when:

- **Summary** - Choose this option to share a brief summary of your recent BlueStar activity when requested by your healthcare provider’s office. This version does not include all of your blood glucose readings.
- **Summary and Logbook** – Choose this option to share a brief summary of your recent BlueStar activity including all your entries for the past 30 days with your healthcare provider’s office.
- **Full Report** – Choose this option to share a full report that includes all the information you entered into BlueStar including your full medication list and health information. Reserve this report for an annual physical or when your healthcare provider’s office requests it.
- **7-Day Food Diary** – Includes a detailed record of your food entries and related notes for a 7-day period

The patient will be prompted to enter the date of their next appointment with their care team and can schedule an appointment reminder. If an appointment reminder is scheduled, the patient will be prompted to schedule their SMART Visit Report to be sent on this date. The patient will be prompted prior to the scheduled SMART Visit Report to update their health information and meds.

The patient can choose to send a SMART Visit report to their health care team and/or to themselves or other selected recipients. Patients will receive reports sent to themselves in their Message section in the Message category, “SMART Visit Reports”.

Patients can schedule a SMART Visit Report to be sent automatically to their health care team and/or themselves at a future date (such as prior to their next health care team visit). The patient can select how often they want the report to be automatically sent (Once, Monthly, or Every 3 Months). After 6 times, the SMART Visit report must be rescheduled.

Patients can view the “Learn about SMART Visit” video to learn more about the SMART Visit Reports including what it is, how it can be used in partnership with the health care team and how to schedule and send SMART Visit Report.

Patients can view a sample SMART Visit Report.

SMART Visit Reports that have been sent can be viewed under “Previous Reports”.

**From the Web:** Click on the Health Info tab > SMART Visit Report tab to select a report to send

**From the Mobile:** Go to Menu and tap on Health Information > SMART Visit report to send

For guidance in setting up and sending the SMART Visit Report, refer to the User Guide:
Care Process Notes:

- Assume the SMART Visit Report is inserted into the work flow and is shared as needed with appropriate team members.

Getting Help

For guidance in navigating Help, refer to the User Guide:

- Page 34

Click the Help link from the top menu bar of the web portal or from the menu in mobile:

- Videos (Learn how to use BlueStar)
- Frequently Asked Questions
- User Guide
- Contact Us: For additional information, contact Customer Care via phone available on Monday-Friday, 8:00 AM – 6:00 PM EST
- About: Product version and unique identifier
- Privacy Policy
- Terms of Use

Module 6: Ongoing Patient & Team Engagement/Diabetes Education

A regularly scheduled series of in-app notifications and emails will be sent to user based on their level of engagement on an ongoing basis.

Care Process Notes:

AADE7 Self-Management Behaviors + Digital Support = Self-Management

At ongoing visits and touch points with patient using BlueStar:

- Review patient’s use of BlueStar
- Determine if patient has an appointment with their healthcare provider scheduled
- Coach patient in preparing for their visit (top concerns and questions, refills needed)
- Ensure patient has scheduled or has sent a SMART Visit Report prior to the visit
- Suggest adding new BlueStar feature(s) to expand use guided by patient preference (reference the BlueStar Digital AADE7 Self-Management Behavior Guide)
Additional Information

**BG Types (general guidelines)**

<table>
<thead>
<tr>
<th>BG Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting</td>
<td>Typically in the morning; no food or drink in at least 8 hours</td>
</tr>
<tr>
<td>Before Meal</td>
<td>Before breakfast, lunch, dinner (from 45 minutes before up to meal)</td>
</tr>
<tr>
<td>After Meal</td>
<td>After breakfast, lunch, or dinner (1.5 – 2 hours after meal)</td>
</tr>
<tr>
<td>Before/After Exercise</td>
<td>Before exercise/ASAP after exercise</td>
</tr>
<tr>
<td>Just Checking</td>
<td>Anytime a patient wants to check a BG</td>
</tr>
<tr>
<td>Snack</td>
<td>Before having a snack</td>
</tr>
<tr>
<td>Bedtime</td>
<td>Before going to bed</td>
</tr>
</tbody>
</table>

**Blood Glucose Targets:**

On the Service Request Form completed by the provider when completing the RX Authorization and selecting the desired A1C target (7.0% or < 8.0%) for the patient: is the following statement:

* The American Diabetes Association states that less stringent glycemic goals may be appropriate in patients with a history of severe hypoglycemia, limited life expectancy, advanced macrovascular or microvascular complications and extensive comorbid conditions, and in those with longstanding diabetes in whom the general goal is difficult to attain despite DSME, appropriate glucose monitoring, and effective doses of multiple glucose lowering agents
including insulin. Certification of blood glucose targets enables BlueStar to send appropriate feedback and recommendations about blood glucose management to the patient;

Based on the A1C target selected, the following BG targets are displayed in BlueStar:

- **Mealtime Targets:**
  - Before meals 80-130 mg/dL (for target A1C of < 8.0%): 90-150 mg/dL
  - After meals 80-179 mg/dL (for target A1C of < 8.0%): 90-200
  - Bedtime: 100-180 mg/dL
  - BlueStar® Messaging addresses both in target and above target

- **Just checking, Snacks, Exercise, Bedtime**
  - These targets are not explicit in the ADA guidelines and are dependent on multiple factors. BlueStar™ messaging is educational and encourages the patient to problem solve or have further conversation regarding their specific targets.

- **Safety Targets:**
  - <70 mg/dL is considered hypoglycemia regardless of reading type. Given concerning signs and symptoms, when to call doctor or 911, BG Re-check countdown is 15 minutes. The Re-check BG reminder remains for 30 minutes after timer reaches 0:00.
    - 51-69 mg/dL: Given 15-15 rule for fast acting carbs
    - < 50 mg/dL: Given 30-15 rule for fast acting carbs
  
  - ≥300 mg/dL is considered very high regardless of reading type: Given tips on lowering BG, concerning signs and symptoms, when to call doctor or 911, what to avoid doing (i.e. be careful/avoid strenuous exercise). Optional: Start 3-hour timer to re-check BG in 3 hours. The Recheck BG reminder remains for 45 minutes after timer reaches 0:00.

  - ≥400 mg/dL is considered to be critically high regardless of reading type: Given tips on lowering BG, concerning signs and symptoms, when to call doctor or 911, what to avoid doing (i.e. be careful/avoid strenuous exercise). Optional: Start 3 hour timer to re-check BG in 3 hours. The Recheck BG reminder remains for 45 minutes after timer reaches 0:00.
### Messaging Behavioral Objectives:

<table>
<thead>
<tr>
<th>Objective</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase Knowledge</td>
<td>Provide basic, practical information needed to adhere to medications and perform related self-management behaviors</td>
</tr>
<tr>
<td>Improve Skills</td>
<td>Define specific tasks that support medication adherence</td>
</tr>
<tr>
<td></td>
<td>Provide tips for incorporating medication-taking into daily life</td>
</tr>
<tr>
<td>Address Barriers</td>
<td>Address common lifestyle, psychosocial, or medical reasons why an individual may not adhere to medications</td>
</tr>
<tr>
<td>Motivate</td>
<td>Highlights external or intrinsic factors that can be used to encourage actions (may include health or non-health benefits)</td>
</tr>
<tr>
<td>Prompt/Reinforce Action</td>
<td>Explicitly encourage supporting actions, the small do-able and specific tasks to support medication adherence</td>
</tr>
<tr>
<td>Show Empathy</td>
<td>Validate feels or emotions (both positive and negative) related to adhering to medications or other related self-management behaviors</td>
</tr>
</tbody>
</table>

### Note regarding use of BlueStar when not connected:

*BlueStar can be used on a phone or tablet to make entries and get messages in real time, even when the user is not connected wirelessly (i.e. airplane mode, lack of cell service). Please note that the user must be connected with wi-fi or cellular service to add a new medication, update health information, send a SMART Visit Report, search in restaurant helper, or view a video. When the user connects to the network, all the entries made in the BlueStar mobile app will be added to the BlueStar system.*
Appendix A: Population Health Management Portal

The BlueStar Ecosystem includes:
- The automated in-app coaching platform for individuals living with type 2 diabetes
- Clinical Decision Support through in-app generated SMART Visit Report for the health care team
- Population level data and messaging capability through the Population Health Management Portal for project stakeholders supporting quality and practice improvement initiatives.

BlueStar’s coaching platform includes:
- Initial and ongoing engagement out of app dynamic messaging (emails, mobile notifications), customer care or care team outreach as well as app prompts and messages
- The automated individualized (tailored) intervention coaching through: smart prompts, reminders, RTF, Pattern coaching, Weekly insights, curriculum.
- Data-driven care team coaching is facilitated by summarized individual user level data through the SMART Visit report and individual and population level data through the population health management portal.

The BlueStar Coaching Platform is designed to empower an engaged, informed patient prepared to interact with their informed and activated care team. The platform facilitates true shared decision making, timely collaborative care plan optimization leading to improved clinical and quality of life outcomes.

Data-Driven Population Management Framework:

View: entire population of registered BlueStar users

Evaluate:
Filter or sort population based on account and/or parameter of concern e.g.
- experiencing hypoglycemic excursions
- last engaged > 7 days ago
- out of date eye exam
Review individual level data as needed for action (using the Population Health Management Portal or the SMART Visit Report).

Communicate:
- Send a tailored message (to individuals or groups)
- Following protocol, document care plan changes

Access to the Population Health Management Portal
Identified clinicians and stakeholders are provided administrative or clinical log-in credentials to the portal. Login requires 2-factor authentication which are then edited by the end user in Settings.

Upon log-in user will be prompted with an initial passcode (Verification Code) which is sent in an email.
The 2-factor authentication resets every time the user logs in unless the user checks the box indicating “Don’t ask me OTP for next 30 days”.

Clinical View includes: Patient List, Emails, and Messages tabs.

Administrative View includes: Patient List, Access Codes, Emails, Messages tabs (the administrative user can generate Access Codes to provide to patients)

**Patient List**
The Patient List includes a list of BlueStar users in the user’s population including sortable tabs with the following information:

- Name
- DOB
- Number of blood glucose readings
- Average blood glucose readings
- < 70 mg/dL
- ≥ 300 mg/dL
- BP
- Cholesterol
- Last BG upload
- Product Status
- Last log-in date

From the Patient List, for each individual patient, the following functions can be performed:

- Generate a SMART Visit Report
- Deactivate the patient
- Send a message (email or within product message)

An individual patient can be selected providing the following data views:

**Overview**: Demographics and BG Summary
The clinician can evaluate:

- Date of last log in
- Last time sent report
- # Readings/Day, Average BG
- Glucose excursions
- Recorded treatment plan

**Logbook**: Detailed logbook with all entries listed with time of day and any notes recorded
The clinician can evaluate:
• How often/when is the individual logging BG?
• What other daily diabetes care factors are being tracked?
• Based on the data tracked, determine if medication or care plan changes are needed
• If not tracking, explore barriers

**Medications:** List of medications the patient has entered into their BlueStar account
The clinician can evaluate and address:
• Concerns regarding taking meds as prescribed
• Determine if med reminders are needed/set
• Assure the BlueStar schedule in app matches daily routine
• Negotiate needed changes in care plan w/ individual, team

**Health Information:** List of out of target/overdue results (A1C, BP, LDL, Eye Exam, Foot Exam, Influenza Vaccine
The clinician can evaluate:
• If clinical data is missing or overdue
• Provide individual w/ lab results or access to patient portal if applicable
• Coach individual in ways to address out of target results or missing measures

**Population Filters**
The entire population of BlueStar users can be filtered for the following conditions:
• Age groups
• A1C target (<7.0% or < 8.0%)
• Most recent recorded A1C level (< 7.0%, 7-8.0%, 8-9.0%, > 9.0%)
• Standards of Care measures: A1C, BP, LDL Chol, Eye Exam, Foot Exam)
• BG events: (<70 mg/dL, ≥ 300 mg/dL)
• Product Status: Active or Inactive
• Last SMART Visit Report sent: <30 days, 31-60 days, 61-90 days, > 90 days
• Last Logged In (Days): <7, 8-15, 16-30, 30-45, > 45
• Gender
• Platform: Android, iPhone, Web
• No Entry: BG, Meds, Food, Activity
• Treatment Plan: Lifestyle Therapy only, Oral or non-insulin injectable, Basal insulin +/- oral/non-insulin injectable, Basal + bolus insulin (+/-orals/non-insulin injectable), No meds profile setup
• View patients by Account
• Name

Filter for only 1 condition at a time.
Clinicians can evaluate:

- Which individuals have met their A1C/BP/LDL targets?
- Which are overdue on eye/foot exams?
- Which individuals are experiencing BG excursions?
- When did individuals last log-in to BlueStar? Send a SMART Visit Report?
- Determine if it would be helpful to send the filtered population an email or message

**Sending emails or messages**

Emails or messages may be sent to all patients, filtered patients, selected patients, individual patients

Templates can be created and selected

Variables (Full name, middle name, last name, long-acting insulin, short-acting insulin, medication name) can be selected allowing personalized messages to be sent to an entire group of patients.

**Note:** If the BlueStar user has selected “Unsubscribe to email” within the app, the Portal user may select “Respect Patient Privacy Setting” and the email will not be sent. However, if Portal user determines the email of importance for BlueStar user to receive, the Portal user may deselect the “Respect Patient Privacy Setting” and the email will be sent.

**Technology-enabled population health**

**Facilitates self-management**

- Using technology and the appropriate level of human touchpoints to deliver contextualized, individualized diabetes self-management care, education, and ongoing support

**Supports shared decision making**

- Links patients to their own care teams, supports timely care plan optimization

**Creates practice improvement opportunities**

- Extends the reach, effectiveness, and efficiency of the care team