

**Therapeutic Use Justification Form**  
**CONTOUR®NEXT ONE for use with the Omnipod DASH™ Insulin Management System**

*Please complete all information in fields on pages 1 and 3.  
Healthcare Provider: please send pages 1-6 to the plan along with your medical justification documentation. Sending pages 7-8 is optional but highly recommended.*

Date (mm/dd/yyyy):	<input type="text"/>
<b>Patient Information</b>	
Patient Full Name:	<input type="text"/>
DOB (mm/dd/yyyy):	<input type="text"/>
Age:	<input type="text"/>
Diabetes Type:	<input type="radio"/> <b>Type 1</b> <input type="radio"/> <b>Type 2</b> <input type="radio"/> <b>Gestational</b>
Years With Diabetes:	<input type="text"/>
Testing per Day:	<input type="text"/>
BGM System Used:	<b>CONTOUR®NEXT ONE Blood Glucose Monitoring System (BGMS)</b>
Insurance Name:	<input type="text"/>
Insurance ID Number:	<input type="text"/>

**Re: CONTOUR®NEXT Test Strips for the CONTOUR®NEXT ONE BGMS**

**ATTN: Medical Director**

**I am writing to seek your approval in prescribing CONTOUR®NEXT Test Strips. Below please find the therapeutic use justification for the CONTOUR®NEXT ONE BGMS to be used with the Omnipod DASH™ Insulin Management System from Insulet.**

The CONTOUR®NEXT ONE BGMS is recommended for use with the Omnipod DASH™ Insulin Management System when blood glucose (BG) results are used for insulin bolus calculation. If the HCP recommends a Continuous Glucose Monitoring System (CGMS) as part of the patient's insulin pump therapy, the CONTOUR®NEXT ONE BGMS may also be used for calibration.

Please note that the CONTOUR®NEXT ONE BGMS is the only BGMS labeled as part of the Omnipod DASH™ Insulin Management System. This BGMS is included with the Omnipod DASH™ System. CONTOUR®NEXT ONE is the only BGMS compatible for pairing with the Omnipod DASH™ Personal Diabetes Manager (PDM) and the CONTOUR®NEXT test strips are the only test strips that work with the CONTOUR®NEXT ONE BGMS.

CONTOUR®NEXT ONE will transfer blood glucose readings via Bluetooth® wireless technology to the PDM of the Omnipod DASH™ Insulin Management System which eliminates manual BG data entry mistakes. This is important because a manual BG entry mistake may result in an incorrect insulin bolus calculation by the pump.

Therefore, wireless transmission of BG data to the insulin pump is not only more convenient for the patient, but also ensures accurate BG data capture by the insulin pump.

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Additionally, BG tests\* that the patient conducts using the wirelessly transmitting CONTOUR®NEXT ONE BGMS are stored in the patient's Omnipod DASH™ PDM and can be viewed using an Insulet-provided and approved diabetes management software such as Glooko®. This means that low BG values that the patient can self-correct by ingesting carbohydrates (but may choose not to manually input into a PDM since insulin dosing is not required) are captured by the pump and viewable in the software.

In other words, **wireless transmission<sup>1</sup> of BG values does not allow for discrimination during data collection**, which provides the healthcare provider with a more comprehensive assessment of the patient's glycemic control, including information on hypoglycemia that may warrant insulin basal rate adjustments.

### The Importance of Accuracy:

Self-monitoring of blood glucose (SMBG) plays a significant role in diabetes management. Obtaining accurate results is important, as people with diabetes rely on glucose meter readings to titrate insulin doses, calibrate continuous glucose monitoring (CGM) devices, adjust their diet and exercise, and detect and properly manage hypoglycemia and hyperglycemia.<sup>1</sup>

In a study simulating the additional annual risk of hypoglycemia due to meter errors, the use of more accurate meters helped to prevent additional severe hypoglycemic episodes in Type 1 and Type 2 diabetes patients with potential savings for the US health care system of more than \$500 million per year.<sup>2</sup>

In addition, experts agree that accurate BGMS readings are important for insulin pump systems to help avoid hypoglycemia, hyperglycemia, and insulin dosing errors.<sup>3</sup>

\*BG tests conducted for the last 90 days.

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# Therapeutic Use Justification Form

## CONTOUR<sup>®</sup>NEXT ONE for use with the Omnipod DASH<sup>™</sup> Insulin Management System

**As such, the performance and accuracy of blood glucose monitoring systems require careful consideration for better diabetes management decision-making.**

The accuracy and performance of the CONTOUR<sup>®</sup>NEXT ONE BGMS has been assessed in the following:

- (1) **Analytical Performance** by Trained Operators and **User Performance Evaluations** in the Hands of Patients using the ISO 15197:2013 accuracy criteria<sup>4,5</sup>
- (2) Performance relative to the accuracy testing requirements per the 2016 FDA BGMS guidelines for OTC Use<sup>6,7</sup>
- (3) Radar Plot analysis to help illustrate the high accuracy and precision demonstrated by the CONTOUR<sup>®</sup>NEXT ONE BGMS<sup>4</sup>

As you will read in the following pages, the CONTOUR<sup>®</sup>NEXT ONE BGMS has been shown to deliver remarkable accuracy within  $\pm 8.4\%$  of lab values.<sup>\*4</sup>

Patient Full Name:	<input type="text"/>
<b>Item: CONTOUR<sup>®</sup>NEXT Test Strips</b>	
<b>Quantity:</b> <input type="text"/> /30 Days – OR – <input type="text"/> /90 Days	
Diagnosis code:	<input type="text"/>
(Select from menu)	

Thank you for your consideration of this matter and for doing everything possible to approve coverage for the CONTOUR<sup>®</sup>NEXT Test Strips.

If you have any questions or require more information, please feel free to contact me.

Sincerely,

### Prescriber Information

Prescriber Name:	<input type="text"/>
Prescriber Title:	<input type="text"/>
Prescriber ID (Select One):	<input type="radio"/> NPI <input type="radio"/> UPIN <input type="radio"/> ME
Number:	<input type="text"/>
Phone:	<input type="text"/>

\* $\pm 8.4\%$  applies to values  $\geq 100$ mg/dL. An ad hoc analysis demonstrated that 95% of results fell within  $\pm 8.4$  mg/dL or  $\pm 8.4\%$  of the laboratory reference values for glucose concentrations  $< 100$  mg/dL or  $\geq 100$  mg/dL, respectively, when tested via subject-obtained capillary fingertip results (patients with diabetes).<sup>4</sup>

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**References:**

- 1 American Diabetes Association. Standards of Medical Care in Diabetes – 2018. Diabetes Care. 2018; 41 (suppl 1) S1:S157.
- 2 Budiman E, Samant N, Resch A. Clinical implications and economic impact of accuracy differences among commercially available blood glucose monitoring systems. J Diabetes Sci Technol. 2013; 7(2):365-380.
- 3 Walsh, et al. New Criteria for Assessing the Accuracy of Blood Glucose Monitors Meeting. Diabetes Science & Technology, 2012 6(2): 466-474.
- 4 Christiansen, M. et al. A New, Wireless-enabled Blood Glucose Monitoring System That Links to a Smart Mobile Device: Accuracy and User Performance Evaluation. J Diabetes Sci Technol. 2017; Vol. 11(3) 567–573.
- 5 International Organization for Standardization. In vitro diagnostic test systems — Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus. Geneva, Switzerland: International Organization for Standardization; 2013.
- 6 Parkes JL, et al. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care. 2000;23(8)1143 – 1148.
- 7 Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Guidance for Industry and Food and Drug Administration Staff; October 11, 2016.
- 8 Christiansen, M. et al. A New, Wireless-enabled Blood Glucose Meter in Development That Links to a Smart Mobile Device via Bluetooth® Connectivity: Accuracy and User Performance Evaluation. Poster presented at The 9th International Conference on Advanced Technologies & Treatments For Diabetes (ATTD); February 3-6, 2016; Milan, Italy.
- 9 International Organization for Standardization. In vitro diagnostic test systems — Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus. Geneva, Switzerland: International Organization for Standardization; 2003.
- 10 Breton MD, Kovatchev BP. Impact of blood glucose self-monitoring errors on glucose variability, risk of hypoglycemia, and average glucose control in type 1 diabetes: an in silico study. J Diabetes Sci Technol. 2010; 4(3):562-570.

# Therapeutic Use Justification Form

## CONTOUR®NEXT ONE for use with the Omnipod DASH™ Insulin Management System

*Healthcare Provider: please send pages 1-6 to the plan along with your medical justification documentation. Sending pages 7-8 is optional but highly recommended.*

### Section 1

#### CONTOUR®NEXT ONE Blood Glucose Monitoring System (BGMS)

The CONTOUR®NEXT ONE BGMS product attributes may help ensure patients are optimizing their Omnipod DASH™ Insulin Management System therapy:

- **The Bluetooth®-enabled CONTOUR®NEXT ONE BGMS** eliminates the need for manual entry of blood glucose readings and BG user entry errors while calculating insulin dosing
- **Second-Chance® sampling**, allows patients to apply more blood which may help prevent wasted test strips and save money
- **No Coding™ technology**, eliminates errors due to user miscoding and can help reduce the number of tests in the testing and training process
- **SmartLIGHT target indicator**, gives patients instant feedback\* and results are easy as red, yellow, and green reference



\*CONTOUR®NEXT ONE User Guide.

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**Table 1**

**CONTOUR®NEXT ONE BGMS Performance Results**

**Results:**

The CONTOUR®NEXT ONE BGMS has been shown to deliver remarkable accuracy within  $\pm 8.4\%$  of lab values.\*<sup>4</sup>

Percentage of highly accurate results (fingerstick testing) <sup>4,5†</sup>			
Glucose concentration	In the hands of	95% of results	Within $\pm 15\%$
$\geq 100$ mg/dL	Patients (n=255)	Within $\pm 8.4\%$	99.6%
	Trained study staff (n=257)	Within $\pm 8.5\%$	100%
Glucose concentration	In the hands of	95% of results	Within $\pm 15$ mg/dL
$< 100$ mg/dL	Patients (n=74)	Within $\pm 8.4$ mg/dL	98.6%
	Trained study staff (n=75)	Within $\pm 8.5$ mg/dL	98.7%

**The CONTOUR®NEXT ONE meter was also proven highly accurate by meeting the ISO 15197:2013 accuracy requirements.<sup>4,5</sup>**



**Note on accuracy standards:**

Until January 30, 2014, the US FDA recognized the ISO 15197:2003 standard, which required the following minimal accuracy acceptability criteria:

- 95% of results to fall within  $\pm 20\%$  of a laboratory reference value for blood glucose concentrations  $\geq 75$  mg/dL and
- 95% of results to fall within  $\pm 15$  mg/dL of a laboratory reference value for blood glucose concentrations  $< 75$  mg/dL.<sup>9</sup>

\* $\pm 8.4\%$  applies to values  $\geq 100$ mg/dL. An ad hoc analysis demonstrated that 95% of results fell within  $\pm 8.4$  mg/dL or  $\pm 8.4\%$  of the laboratory reference values for glucose concentrations  $< 100$  mg/dL or  $\geq 100$  mg/dL, respectively, when tested via subject-obtained capillary fingertip results (patients with diabetes).<sup>4</sup>

†Data based on routine finger sticks vs. lab method.

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**Therefore, the allowable margin of error of some BGMSs available on the market today can be up to  $\pm 20\%$  for glucose levels  $\geq 75$  mg/dL. A  $\pm 20\%$  margin of error could lead patients to take the wrong course of action to correct their blood sugar.<sup>10</sup>**

Regulatory agencies and other stakeholders have pushed for a tighter accuracy standard.

First, the ISO 15197:2013 standard was published, a tightened accuracy standard which requires :

- 95% of results to fall within  $\pm 15$  mg/dL of a laboratory reference value for blood glucose concentrations  $< 100$  mg/dL,
- 95% of results to fall within  $\pm 15\%$  of a laboratory reference value for blood glucose concentrations  $\geq 100$  mg/dL, and
- 99% of individual glucose measured values shall fall within Zones A and B of the Consensus Error Grid.<sup>5,6</sup>

#### **2016 FDA BGMS guidelines for OTC Use:**

In January 7, 2014, the FDA released draft guidance for BGMS accuracy that was finalized on October 11, 2016 and now requires far more accuracy and precision from BGMSs. The guidance document requires that there be smaller errors in the hypoglycemic range and fewer outliers, allowing only 5% of measurements to have an error larger than  $\pm 15\%$  and 1% of measurements to have an error greater than  $\pm 20\%$  above or below the reference value, rather than the 5% of measurements greater than  $\pm 20\%$  permitted under the 2003 ISO Guidelines.<sup>7</sup>

The CONTOUR®NEXT ONE BGMS has been shown to be highly accurate against the accuracy requirements outlined in the 2016 SMBG FDA guidelines for fingertip and Alternative Site Testing (AST),<sup>8</sup> which stipulates:

- 95% of results should be within  $\pm 15\%$  of the laboratory reference values (comparator) across the entire claimed measuring range, and
- 99% of results should be within  $\pm 20\%$  of the laboratory reference values (comparator) across the entire claimed measuring range

In addition to the aforementioned more robust performance requirements, which include tighter hypoglycemia accuracy, the FDA SMBG guideline calls for additional requirements concerning interferences, hematocrit, environmental conditions, labeling, among others.<sup>7</sup>

In conclusion, the CONTOUR®NEXT ONE BGMS has been shown to deliver remarkable accuracy within  $\pm 8.4\%$ \* of lab values. In addition, it has been proven highly accurate relative to the accuracy testing requirements set forth in the 2016 FDA BGMS guidelines for OTC use.<sup>4,5,8</sup>

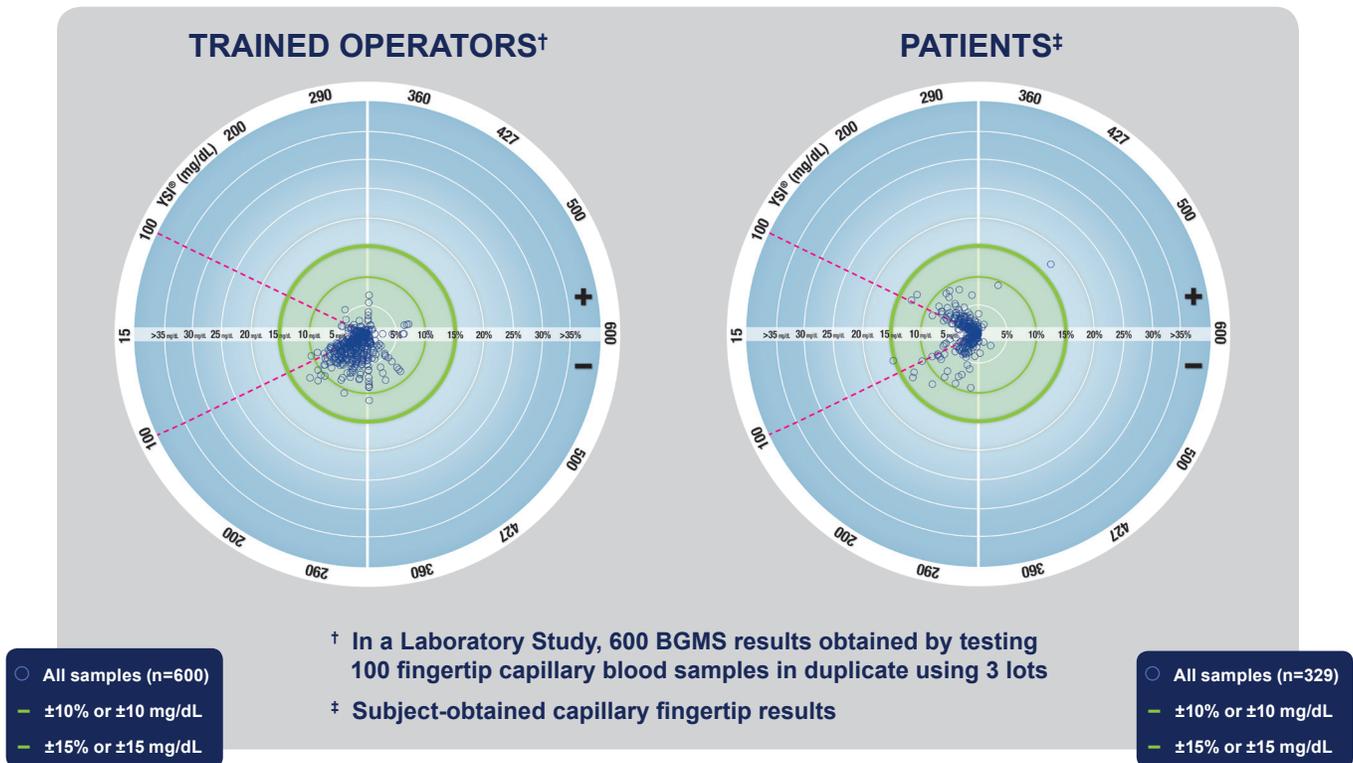
Ascensia Diabetes Care places the highest priority on accuracy you can trust, to help patients and healthcare providers make better diabetes management decisions.

\* $\pm 8.4\%$  applies to values  $\geq 100$ mg/dL. An ad hoc analysis demonstrated that 95% of results fell within  $\pm 8.4$  mg/dL or  $\pm 8.4\%$  of the laboratory reference values for glucose concentrations  $< 100$  mg/dL or  $\geq 100$  mg/dL, respectively, when tested via subject-obtained capillary fingertip results (patients with diabetes).<sup>4</sup>

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## CONTOUR®NEXT ONE BGMS Radar Plots

Radar Plot illustrating the high accuracy and precision of the CONTOUR®NEXT ONE BGMS<sup>4</sup>



### Radar Plot description:

A Radar Plot is a way to show the difference between BGMS and the laboratory reference (YSI) values in BGMS performance evaluations.

### ISO 15197: 2013 Performance:

The outer green circle known as the 15-15 Zone (15 mg/dL or 15%) illustrates how the BGMS performs relative to the accuracy requirements set forth by ISO 15197:2013.

### Accuracy & Precision:

Accuracy on the graph is represented by how close the data points are to the center; the closer the points are to the center, the more accurate. Precision, on the other hand, is represented by how the dots fall on top of each other; the more spread out, the less precise.

The tight clustering of data points in the center of the radar plot for the CONTOUR®NEXT ONE BGMS provides a visual indicator of the analytical accuracy and precision of this BGMS.