Therapeutic Use Justification Form

CONTOUR®NEXT LINK 2.4 for use with the MiniMed™ 630G and MiniMed™ 670G insulin pump systems

PLEASE COMPLETE ALL INFORMATION FIELDS ON PAGES 1 AND 3.
HEALTHCARE PROVIDER: PLEASE SEND PAGES 1-6 TO THE PLAN. SENDING PAGES 7-10 IS OPTIONAL BUT HIGHLY RECOMMENDED.
Form can be provided in addition to and does not replace the Medical Necessity Justification signed by the healthcare provider.

Date (mm/dd/yyyy):	
Patient Information	
Patient Full Name:	
DOB (mm/dd/yyyy):	
Age:	
Diabetes Type:	◯ **Type 1** ◯ **Type 2** ◯ **Gestational**
Years With Diabetes:	
Testing per Day:	
BGMS Used:	**CONTOUR®NEXT LINK 2.4 Blood Glucose Monitoring System (BGMS)**
Insurance Name:	
Insurance ID Number:	

Re: **CONTOUR®NEXT Test Strips for the CONTOUR®NEXT LINK 2.4 Blood Glucose Monitoring System (BGMS)**

ATTN: Medical/Pharmacy 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 LINK 2.4 BGMS to be used with either Medtronic's MiniMed™ 630G system or with the MiniMed™ 670G system.

CONTOUR®NEXT LINK 2.4 is the only FDA-approved (Pre-Market Approval or PMA) linking BGMS for use with Medtronic's MiniMed™ 630G and MiniMed™ 670G systems, and only CONTOUR®NEXT LINK 2.4 has met the more rigorous review scrutiny required for a Class III FDA-approved (Pre-Market Approval or PMA) BGMS as part of an integrated artificial pancreas device system (APDS).[1] PMA is the most stringent type of device marketing application required by the FDA. Unique to Class III BGMSs are tight manufacturing controls and stringent change management requirements closely monitored by the FDA. The CONTOUR®NEXT LINK 2.4 is the only BGMS in the marketplace today shown to fulfill these obligations and was FDA-approved as part of the MiniMed™ 630G and MiniMed™ 670G systems.

Please note that the CONTOUR®NEXT LINK and CONTOUR®NEXT LINK 2.4 BGMSs are the only linking meters being provided with Medtronic insulin pumps,* and the CONTOUR®NEXT Test Strips are the only test strips that work with the CONTOUR®NEXT LINK and the CONTOUR®NEXT LINK 2.4 BGMSs.

* CONTOUR®NEXT LINK 2.4 is the only FDA-approved meter for use with the MiniMed™ 630G and MiniMed™ 670G systems. The CONTOUR®NEXT LINK Meter is compatible with the MiniMed™ 530G system and with the MiniMed™ Paradigm™ REAL-Time Revel™ insulin pumps.

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The MiniMed™ 630G and MiniMed™ 670G systems require BG results obtained from the CONTOUR®NEXT LINK 2.4 BGMS for continuous glucose monitoring (CGM) system calibration and insulin bolus calculation.† More specifically, the MiniMed™ 670G system features the Guardian™ Sensor 3, Medtronic's newest and most advanced glucose sensor with enhanced accuracy and performance and a longer 7-day life. Guardian™ Sensor 3 is the first and only sensor approved by the FDA to control a hybrid closed loop system. The Mean Absolute Relative Difference (MARD) of the Guardian Sensor 3 when used with the MiniMed 670G system has been demonstrated to be 8.68% (arm insertion) when calibrating 3 to 4 times/day with the CONTOUR®NEXT LINK 2.4 BGMS.*

CONTOUR®NEXT LINK 2.4 BGMS also wirelessly transmits blood glucose results to the patient's Medtronic insulin pump, **which eliminates manual BG data entry mistakes to the pump.** 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.

Lastly, every BG test the patient conducts using the automatic wirelessly transmitting CONTOUR®NEXT LINK 2.4 BGMS is stored in the pump and can be viewed using the Medtronic MiniMed™ CareLink® therapy management software. This means low BG values that the patient can self-correct by ingesting carbohydrates (but may choose not to manually input into a pump since insulin dosing is not required) are captured by the pump and viewable in the software.

In other words, **automatic wireless transmission‡ of BG values does not allow for discrimination during data collection,** which can provide healthcare providers 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.[2]

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.[3]

In addition, experts agree that accurate BGMS readings are important for insulin pump systems to help avoid hypoglycemia, hyperglycemia, and insulin dosing errors.[4]

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† Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an Alternative Site (palm) or from a control solution test. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise.
‡ CONTOUR®NEXT LINK 2.4 Wireless Blood Glucose Monitoring System User Guide. See Page 10: "Meter Send Options".
If **Always** was selected in the **Send Options;** the meter will always send results to the MiniMed 630G and MiniMed 670G insulin pumps.
*Medtronic Diabetes. Data on file.

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®NEXT LINK 2.4 BGMS has been assessed in the following:

(1) ***Analytical Performance*** by *Trained Operators* and ***User Performance Evaluation*** in the *Hands of Patients* using the ISO 15197:2013 accuracy criteria[5,6]

(2) Performance relative to the accuracy testing requirements per the 2016 FDA BGMS guidelines for OTC Use[7,8]

(3) Radar Plot analysis to help illustrate the high accuracy and precision demonstrated by the CONTOUR®NEXT LINK 2.4 BGMS[5,8]

As you will read in the following pages, the high accuracy and precision demonstrated by the CONTOUR®NEXT LINK 2.4 BGMS has helped to close the gap between laboratory accuracy and real-word test results.[5]

I am writing to seek your approval in prescribing CONTOUR®NEXT Test Strips:

Patient Full Name: _____
Item: CONTOUR®NEXT Test Strips
Quantity: ____ /30 Days – OR – ____ /90 Days
Diagnosis code: **type 1 diabetes with misc. complications 250.93 (uncontrolled)**
(Select from menu)

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

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

Sincerely,

Prescriber Information
Prescriber Name: _____
Prescriber Title: _____
Prescriber ID (Select One): ◯ NPI ◯ UPIN ◯ ME
Number: _____
Phone: _____

References:

1. Food and Drug Administration. The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA). Applications for Artificial Pancreas Device Systems: US FDA Guidance; 2012.

2. American Diabetes Association. Standards of Medical Care in Diabetes—2015.Diabetes Care. 2014; 37 (suppl 1):S14-S80.

3. 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.

4. Food and Drug Administration. Walsh, et al. New Criteria for Assessing the Accuracy of Blood Glucose Monitors Meeting Diabetes Science & Technology, 2012 6(2): 466-474.

5. Bailey J WJGC. Accuracy and User Performance Evaluation of the CONTOUR®NEXT LINK 2.4 blood glucose monitoring system. Clinica Chimica Acta. 2015(448):139 -145.

6. 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.

7. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Guidance of Industry and Food and Drug Administration Staff; October 11, 2016.

8. Data on File. Ascensia Diabetes Care.

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.

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Important Safety Information: MiniMed® 670G System

The Medtronic MiniMed™ 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed™ 670G system includes SmartGuard™ technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The system requires a prescription. The Guardian™ Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. A confirmatory finger stick test via the CONTOUR®NEXT LINK 2.4 blood glucose meter is required prior to making adjustments to diabetes therapy. All therapy adjustments should be based on measurements obtained using the CONTOUR®NEXT LINK 2.4 blood glucose meter and not on values provided by the Guardian™ Sensor (3). Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the CONTOUR®NEXT LINK 2.4 blood glucose meter. Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an Alternative Site (palm) or from a control solution test. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise. If a control solution test is out of range, please note that the result may be transmitted to your pump when in the “Always” send mode.
WARNING: Medtronic performed an evaluation of the MiniMed 670G™ system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely.
Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. The safety of the MiniMed™ 670G system has not been studied in pregnant women. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult **http://www.medtronicdiabetes.com/important-safety-information#minimed-670g** and the appropriate user guide at **http://www.medtronicdiabetes.com/download-library**

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CONTOUR®NEXT LINK 2.4 BGMS Performance and Accuracy results:

- **ISO 15197:2013 Performance Table** shows how the CONTOUR®NEXT LINK 2.4 BGMS has demonstrated highly accurate results in the hands of trained operators and in the hands of patients.

- The CONTOUR®NEXT LINK 2.4 BGMS has been demonstrated highly accurate against the accuracy requirements outlined in the **2016 FDA BGMS guidelines for OTC Use.**

- The **CONTOUR®NEXT LINK 2.4 BGMS Radar Plots** illustrate the high accuracy of the CONTOUR®NEXT LINK 2.4 BGMS in the hands of trained operators and in the hands of patients.

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CONTOUR®NEXT LINK 2.4 BGMS: Performance Results Relative to the ISO 15917:2013 and the 2016 FDA BGMS accuracy testing requirements.[4,5,7,8]

Results:

The CONTOUR®NEXT LINK 2.4 BGMS has demonstrated highly accurate results close to laboratory reference values [5]

CONTOUR®NEXT LINK 2.4

Percentage of highly accurate results			
Glucose concentration	In the hands of	Within ± 10%	Within ± 15%
≥ 100 mg/dL	Trained operators	**99.3%** (411/414)	**100%** (414/414)
	Patients†	**93.5%** (172/184)	**98.4%** (181/184)
Glucose concentration	In the hands of	Within ± 10 mg/dL	Within ± 15 mg/dL
< 100 mg/dL	Trained operators	**98.4%** (183/186)	**100%** (186/186)
	Patients†	**100%** (34/34)	**100%** (34/34)

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 ±20% of a laboratory reference value for blood glucose concentrations ≥75 mg/dL and
- 95% of results to fall within ±15 mg/dL of a laboratory reference value for blood glucose concentrations <75 mg/dL.[9]

† Data based on routine finger sticks vs. lab method. The ISO 15197:2013 standard requires 95% of results to fall within ±15 mg/dL of a laboratory reference value for blood glucose concentrations <100 mg/dL and within ±15% of a laboratory reference value for blood glucose concentrations ≥100 mg/dL, and 99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid for type 1 diabetes. In the hands of users, 95% of the individual glucose measured values shall fall within ±15 mg/dL of the measured values of the manufacturer's measurement procedure at glucose concentrations <100 mg/dL and within ±15% at glucose concentrations ≥100 mg/dL.[6]

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Therefore, the allowable margin of error of BGMSs available on the market today can be up to ±20% for glucose levels ≥75 mg/dL. A ±20% margin of error could lead patients to take the wrong course of action to correct their blood sugar.[10]

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

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

- 95% of results to fall within ±15 mg/dL of a laboratory reference value for blood glucose concentrations <100 mg/dL,

- 95% of results to fall within ±15% of a laboratory reference value for blood glucose concentrations ≥100 mg/dL, and

99% of individual glucose measured values shall fall within Zones A and B of the Consensus Error Grid.[6]

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 ±15% and 1% of measurements to have an error greater than ±20% above or below the reference value, rather than the 5% of measurements greater than ±20% permitted under the 2003 ISO Guidelines.[7]

The CONTOUR®NEXT LINK 2.4 Meter has been demonstrated to be highly accurate against the accuracy requirements outlined in the 2016 SMBG FDA guidelines for fingertip and Alternative Site Testing (AST),[7] which stipulates:

- 95% of results should be within ±15% of the laboratory reference values (comparator) across the entire claimed measuring range, and

- 99% of results should be within ±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.[7] To our knowledge, no BGMS on the marketplace today fully meets the FDA SMBG guidance as written.

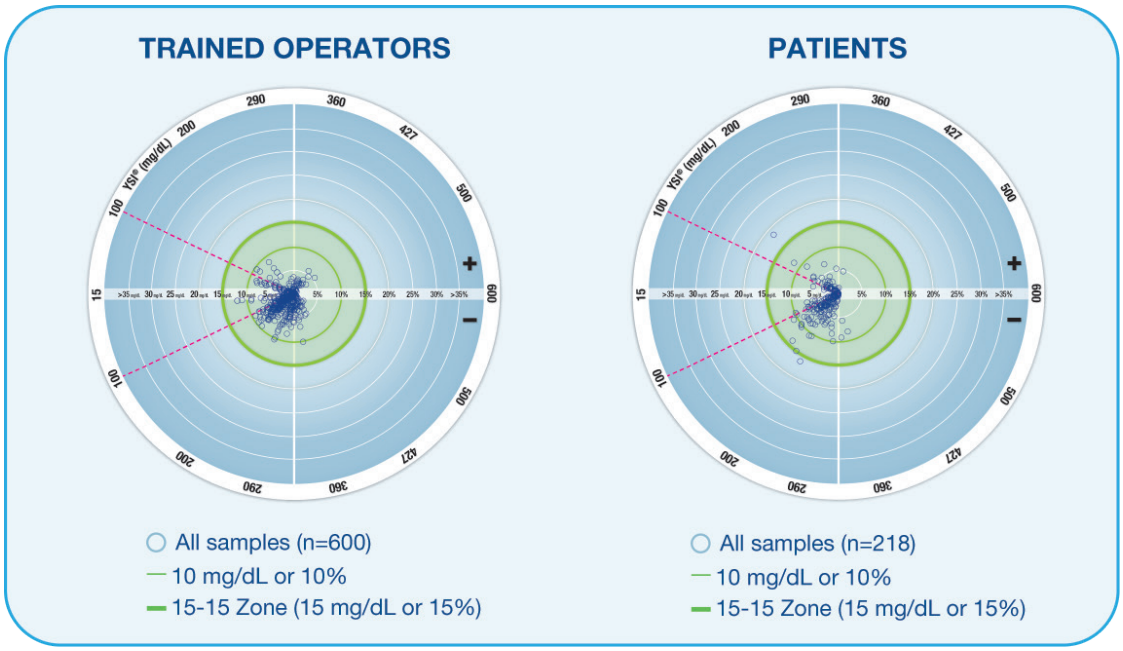
In conclusion, the CONTOUR®NEXT LINK 2.4 BGMS has been proven highly accurate and precise by meeting the ISO 15197:2013 accuracy standard [5,6] and relative to the accuracy testing requirements in the 2016 FDA BGMS guidelines for OTC use.[7,8]

Ascensia Diabetes Care places the highest priority on accuracy you can trust, to help you, as well as your patients, make better diabetes management decisions.

CONTOUR®NEXT LINK 2.4 BGMS Radar Plots

Results:

Radar Plot illustrating the high accuracy and precision of the CONTOUR®NEXT LINK 2.4 BGMS[5,8]



Radar Plot description:

A Radar Plot is a new 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 LINK 2.4 BGMS provides a visual indicator of the analytical accuracy and precision of this BGMS.

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Study Design Information:

Accuracy and User Performance Evaluation of the CONTOUR®NEXT LINK 2.4 BGMS[5]

Objectives:

Two studies were conducted, in the laboratory and in the clinical setting, to evaluate the accuracy of the CONTOUR®NEXT LINK 2.4 blood glucose monitoring system (BGMS).

Methods:

In the laboratory study, fingerstick samples from 100 subjects were tested in duplicate using 3 test strip lots and assessed per ISO 15197:2003 section 7 and ISO 15197:2013 section 6.3 accuracy criteria. In the clinical study, 218 subjects with diabetes completed the study at 2 clinical sites. Subjects naive to the BGMS tested capillary blood from their fingertips and palms; BGMS glucose results were compared with the YSI reference method. Subjects in the clinical setting completed questionnaires on ease of use and diabetes management.

Results:

In the laboratory study, 100% of results met ISO 15197:2003 section 7 and ISO 15197:2013 section 6.3 accuracy criteria. Also, 99% (594/600) of results were within ±10mg/dL or ±10% of the YSI reference method. Regression analysis demonstrated a high degree of agreement between BGMS and reference (R^2=0.9926). In the section 8 clinical study, 100% of subject fingerstick and 99.1% of palm results met ISO 15197:2003 accuracy criteria; 98.6% of subject fingerstick and 97.2% of palm results met ISO 15197:2013 section 8 accuracy criteria. Questionnaire results showed most subjects found the BGMS easy to use.

The high accuracy and precision of the CONTOUR®NEXT LINK 2.4 BGMS has helped to close the gap between laboratory accuracy and real-word test results.