MINIMED® 670G SYSTEM COVERAGE TOOL KIT OVERVIEW FOR CUSTOMERS WITH INSURANCE THAT CURRENTLY DOES NOT COVER THE MINIMED 670G SYSTEM

Medtronic has assembled this tool kit composed of sample documents and information intended to help assist you in pursuing coverage (if you choose to) from your insurance company before you consider purchasing the MiniMed 670G system.

Please be aware that the MiniMed 670G system may not be covered by your insurance. If your health plan does not cover the MiniMed 670G system, you may need to follow the plan’s appeal process. This may be a long process and may include several appeals which both you and your physician will need to pursue.

Every insurance company has different rules and processes. The information provided here should be used as a general guide and as an example only. Be sure to check with your insurance company for their specific documentation needs and processes including who the coverage request must come from as well as the details on how to submit your request.
DOCUMENTS FROM YOUR PHYSICIAN

1. Prescription From Your Physician
Your insurance company will want a copy of your prescription.

2. Letter of Medical Necessity
Ask your physician for a “letter of medical necessity.” The purpose of the letter is to confirm why you (the customer) are a candidate for the MiniMed 670G system and should include:
- A clear explanation of the medical necessity from your prescribing physician including:
  - Your demographics
  - Your diabetes history
  - Any current diabetes-based challenges you are experiencing which the MiniMed 670G system would solve

DOCUMENTS PROVIDED BY YOU (OUR CUSTOMER)

1. Letter From You Requesting Coverage (sample letter included)
Submit a letter from yourself requesting coverage approval. The letter should explain:
- The purpose of the letter (to request coverage for MiniMed 670G system)
- Review your specific medical policy and use the language it contains to describe why the MiniMed 670G system is “medically necessary”
- Personal medical history to demonstrate medical necessity. Provide specific incidences requiring medical intervention which the MiniMed 670G system could likely mitigate
- Request approval for the MiniMed 670G system and ask for the next steps in the process

2. Description of the MiniMed 670G system
Your insurance company will want details about the MiniMed 670G system and how it works. This toolkit includes a description and photos of the system. Please print as necessary to provide information your insurance company may require.
APPEAL PROCESS

Pursuing coverage for new technology may require the patient and physician to file for an appeal. After your initial request for coverage, your insurance company will send you a letter approving your request or denying it. If you receive a denial, review the letter for details on how to submit an appeal. Gather the information your insurance company has asked for and follow the appeal process for that specific company.

Appeal Letter
Submit a letter from yourself requesting an appeal. The letter should include:

- The purpose of the letter (to appeal your coverage request for the MiniMed 670G system)
- Specific mention of the reason your insurance company denied your initial request and documented reasons why the company should re-evaluate
- Any supplemental information your insurance company has requested
- Repeat your request for approval for the MiniMed 670G system

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. Do not 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. Only use rapid acting U100 insulin with this system. 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, including product and important safety information concerning the system and its components, please consult [http://www.medtronicdiabetes.com/important-safety-information#minimed-670g](http://www.medtronicdiabetes.com/important-safety-information#minimed-670g) and the appropriate user guide at [http://www.medtronicdiabetes.com/download-library](http://www.medtronicdiabetes.com/download-library).
SAMPLE CUSTOMER COVERAGE REQUEST LETTER

Date

Name
Insurance Company name
Address
City, State and ZIP Code

Re: [Your Name]
Group number: [#####] Policy number: [#####]

To whom it may concern;

[Provide one to two sentences describing yourself and your condition].

Please accept this letter as a request from [your name] to [Insurance Company name] to review and make a positive coverage determination for the MiniMed 670G system.

This device is for continuous delivery of basal insulin and administration of insulin boluses for the management of type 1 diabetes mellitus.

As you know, I was diagnosed with diabetes on [date].

My healthcare provider has prescribed the MiniMed 670G system due to [healthcare provider to enter medical necessity rationale here for the use of MiniMed 670G]

[In this section, insert why you would benefit from the use of the MiniMed 670G system]

To assist with your initial review, please see the enclosed letter of medical necessity from my physician. Also included is the prescription from my physician and product information explaining the MiniMed 670G System.

I ask that you allow coverage for this device as deemed medically necessary per my physician. Should you require additional information, please do not hesitate to contact me at [provide contact information]. I look forward to hearing from you in the near future.

Sincerely,
[Your Name]
THE WORLD’S FIRST
HYBRID CLOSED LOOP SYSTEM.
MINIMED® 670G SYSTEM.

MINIMED 670G SYSTEM HIGHLIGHTS.
The MiniMed 670G system with SmartGuard® HCL technology offers two new levels of personalization:

The Suspend before low option avoids lows and rebound highs proactively by automatically stopping insulin 30 minutes before a patient reaches his/her pre-selected low limits, then automatically restarts insulin when his/her levels recover, all without bothersome alerts.

Insulin pump suspension in advance of predicted lows* helped patients with type 1 diabetes avoid lows in 83% of the occasions when it was predicted.**

The Auto Mode option automatically adjusts a patient’s basal insulin delivery every 5 minutes based on the patient’s sugar levels to help keep him/her in target range, all day and night.

After three months on the MiniMed 670G system, 75% of people† reduced their A1C.‡ There was no severe hypoglycemia and DKA events during the pivotal trial, a three month non randomized clinical study of 124 patients.‡

** Feature performance based on study data using the MiniMed 640G system, approved only outside the US.


† Data on file.

Actual results are based on clinical trial. Study limitations apply. Individual results may be different.


Exclusive CONTOUR®NEXT LINK
2.4 meter³
Easy and accurate CGM calibration, insulin dosing and remote bolusing with our exclusive meter.

Guardian® Sensor 3 continuous glucose monitoring sensor
Introducing the most accurate sensor from Medtronic, now with up to 7 day wear and easy insertion. It is the first and only continuous glucose monitoring sensor FDA approved and trusted to control insulin dosing.

Indicated for type 1 patients 14 and over. Prescription required.
WARNING: may not be safe for children under 7 or those requiring less than 8 units of insulin per day.

* Measured in sensor glucose.

³ Measured in sensor glucose.

³ Feature performance based on study data using the MiniMed 640G system, approved only outside the US.

Indicated for type 1 patients 14 and over. Prescription required.
WARNING: may not be safe for children under 7 or those requiring less than 8 units of insulin per day.
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. Do not 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. Only use rapid acting U100 insulin with this system. 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, including product and important safety information concerning the 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.

Guardian Sensor (3) The Guardian Sensor (3) is intended for use with the MiniMed 670G system to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns in persons aged fourteen years and older, and to be used by the MiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

One-press Serter The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and is not intended for multiple patient use.

Guardian Link (3) Transmitter The Guardian Link (3) Transmitter is intended for use with MiniMed 670G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 670G insulin pump. The Transmitter is intended for single-patient multi-use.

CONTOUR®NEXT LINK 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single patient use only and should not be shared. The CONTOUR®NEXT LINK 2.4 wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The CONTOUR®NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The CONTOUR®NEXT LINK 2.4 wireless blood glucose transmit glucose values to the MiniMed 670G insulin pump and facilitate transfer of information to Medtronic CareLink® Software through the use of radio frequency communication. The CONTOUR®NEXT LINK 2.4 Wireless Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for, diabetes mellitus. It is not intended for use on neonates.

Contraindications Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Do not use the serter on products other than the Elite sensor or Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products. The reservoir is contraindicated for the infusion of blood or blood products. Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products. Insulin pump therapy is not recommended for those who are unwilling to perform at least four blood glucose tests per day. As insulin pumps use rapid acting insulin only, BG testing is required to help identify rapid glycemic deterioration due to insulin infusion occlusion, infusion site problems, insulin stability issues, user error, or a combination of these. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

General Warnings The safety of the 670G system has not been studied in people with impaired kidney function. Please let your healthcare professional know if you have kidney disease so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks. The safety of the 670G system has not been studied in pregnant women, people with type 2 diabetes, or in people using other anti-hyperglycemic therapies apart from insulin. Please let your healthcare professional know if any of these conditions apply to you so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.

For additional information, please consult the appropriate User Guide.

MiniMed is a registered trademark and SmartGuard is a trademark of Medtronic, MiniMed Inc.

Ascensia, the Ascensia Diabetes Care logo and Contour are trademarks and/or registered trademarks of Ascensia Diabetes Care.

940M16639-012 20170511 © 2017 Medtronic MiniMed Inc, All Rights Reserved.